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Decision Making in Managed Care Organizations: Implications for the Development and Diffusion of New Technologies

Final Report

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BlueCross BlueShield Technology Evaluation Center
Boston Scientific
Brigham and Women's Hospital
Bristol Park Medical Group
Catholic Health Partners
Center for Health Dispute Resolution
CIGNA HealthCare (national headquarters)
CIGNA HealthCare of California
CIGNA HealthCare of Texas
Fallon Health Plan
First Choice Health Plan
GE Medical Systems

Genzyme Genetics
Group Health Cooperative of Puget Sound
Harborview Medical Center
Harvard Pilgrim Health Plan
HealthCare Partners Ltd.
Health Industry Manufacturers Association
Memorial-Hermann Health System
Hewlett-Packard
Kaiser Permanente (national headquarters)
Kaiser Permanente (Southern California)
Medical Alley Associates
Medical Care Ombudsman Program
Medtronic
Memorial Sisters of Charity
Methodist Care
Methodist Health Care System
PacifiCare (national headquarters)
PacifiCare of California
PacifiCare of Texas
Partners Community Health Care
Pfizer, Inc.
Prescription Solutions
Providence Health Plans
Prudential Health Plan
Regence BlueCross BlueShield of Oregon
Smith/Kline Beecham Pharmaceuticals
St. Luke's Episcopal Hospital
Swedish Medical Center
Tufts Health Care Plan
UCLA Medical Center
United HealthCare (national headquarters)
United HealthCare (Chicago)
University of Chicago Hospital
Virginia Mason Medical Center

Executive Summary

Background

The continuing upward spiral of health care spending in the United States has concerned policymakers and analysts for over 25 years. A variety of forces have been posited as drivers of this cost growth, including the aging of the population, rising per capita income, the spread of insurance, and the increased supply of physicians. Although difficult to quantify, many analysts have identified the development and adoption of new technologies as a primary driving force. Technology is an especially potent force because of its interactive relationship with insurance. Expanded insurance coverage has increased health care spending, which encourages research and development (R&D) of new technologies. New technologies directly raise aggregate health spending because, historically, most have been cost increasing. They also exert an indirect effect by increasing demand for insurance and expanding the definition of insurance coverage, which in turn increase demand for services.

It has been suggested that managed care may alter the feedback loop between health insurance and technological innovation, thereby breaking this inflationary spiral. Managed care organizations (MCOs) may be less likely than traditional indemnity plans to cover new technologies or may be better able to control the diffusion of those that are covered. Managed care plans are expected particularly to control the adoption of cost-increasing technologies. As the importance of managed care grows, incentives for R&D investment may shift away from technologies that increase costs without a commensurate improvement in outcomes to those than can demonstrate cost-effectiveness or even reduce costs. The growth in Medicare managed care is particularly significant given the size of this population and its high levels of service use. This study went inside the black box of decision-making on the demand side (MCOs) and the supply side (manufacturers) of the technology equation, using case study interviews to understand the complex relationship between managed care and technology adoption, diffusion, and development. Our definition of technology encompassed procedures, devices, and pharmaceuticals, including biotechnology.

Study Design

On the demand side, our case studies examined decision-making by MCOs regarding the coverage of specific technologies, factors influencing those decisions, mechanisms used to control utilization of covered technologies, and decision-making about product design, including benefit packages, premiums, and cost sharing. We conducted interviews with 18 MCOs in six market areas across the country that varied in managed care penetration. Because of our special interest in the impact of Medicare managed care, all of the interview sites were Medicare+Choice contractors (or, in one case, expected to launch a Medicare product shortly). We also conducted interviews at selected hospitals and large physician groups that bear substantial levels of risk because many important technology adoption decisions are not within the direct purview of MCOs. However, the influence of managed care may be observed indirectly via its impact on decisions made by providers. We also spoke with staff from the national headquarters of five MCOs. Additional interviews were conducted with three types of organizations that have a collateral role in coverage decision-making--technology assessment organizations, pharmacy benefits managers (PBMs), and external review organizations.

Our supply side case studies explored R&D investment decision making in the device and pharmaceutical industries. Our sites included four device manufacturers and three pharmaceutical companies, one of which was a biotechnology firm. We selected manufacturers of technologies with characteristics that varied along dimensions that were expected to impact the influence of managed care, including: visibility to patients; cost-saving vs. cost-increasing; current diffusion level; inpatient vs. outpatient locus; and Medicare orientation. Our interviews addressed the full range of factors expected to drive manufacturer R&D agendas. In addition to managed care generally, and Medicare managed care in specific, these factors included scientific advances, population demographics, world markets, and provider payment policies. We also discussed manufacturer marketing and forecasting strategies.

Findings

MCOs. With the exception of a few small, immature plans, each of the MCOs interviewed had a formal process for making technology coverage decisions. Plans typically only set policy for a small percentage of the new technologies that come on the market because the assessment process is very costly. Assessments are usually targeted at high cost or controversial technologies, although more coverage decisions are made for individual drugs through the process of setting the formulary. MCOs stress the clinical orientation of their technology assessment process and assert that cost is very rarely an explicit consideration. Price is more often a factor in setting drug formularies due to the availability of close or exact substitutes. All plans indicated that they would not refuse to cover a technology that had been generally accepted as the standard of care, no matter how expensive. MCOs rarely incorporate cost-effectiveness analyses in their coverage decisions; instead, they focus on the safety and efficacy of the technology and improvement over existing technologies.

With the exception of technologies considered to be dangerous, ineffective, or unproven (i.e., investigational/experimental), MCOs rarely adopt a blanket no-coverage policy for a technology and, instead, establish medical necessity criteria for its use. However, these guidelines are often based on complex diagnostic indications and treatment history that cannot be incorporated in automated claims processing systems. While plans use prior authorization or utilization review for some technologies, these types of audit mechanisms are labor intensive and too expensive to use routinely. As a result it may be difficult to control "off-label" use of technologies that have been approved for limited indications. Plans face powerful external pressures--from patients, purchasers, politicians, and the media--that make it difficult for them to deny coverage of services. Recent discussions of Patients' Bill of Rights legislation in many states have crystallized these pressures.

Given these constraints on the effectiveness of treatment guidelines, plans are increasingly turning to patient cost sharing, a tool more associated with traditional indemnity insurance, to limit utilization. Cost sharing is particularly widely used for prescription drugs, where plans costs have been escalating rapidly. Plans have also delegated responsibility for managing costs to providers through subcapitation arrangements, although they are facing limits on the number of groups that will accept such arrangements. They also place considerable emphasis on provider education.

Device and Drug Manufacturers. Our case studies of manufacturers indicate that managed care molds R&D in several important ways through coverage and payment policies. First, manufacturers have responded to reduced utilization of inpatient services by shifting R&D dollars to ambulatory care. Second, bundled provider payments, particularly for inpatient care, encourage development of technologies that reduce production costs. Third, especially in pharmaceuticals, MCOs have created price competition among substituting technologies which has spawned a growing emphasis on discovery of "blockbuster" technologies.

However, on a fundamental level, managed care has no impact on several of the key forces driving technological innovation: (1) demographics, particularly the aging of the baby boom generation; (2) the growing importance of world markets; and (3) scientific advances that facilitate breakthrough discoveries. Furthermore, MCOs only influence the adoption of many technologies indirectly through their provider payment incentives. However, even under managed care, providers still face powerful incentives to adopt new technologies.

Although bundled payments, such as per diems and diagnosis related groups (DRGs), encourage hospitals to minimize productions costs, they continue to use technology to compete for both patients and managed care contracts. While some physicians have subcapitation or other risk-sharing arrangements with MCOs most, especially specialists, continue to receive fee-for-service (FFS) reimbursement and maximize their billings by adopting new technologies.

It is also not clear that the changes in R&D engendered by managed care necessarily alter the feedback relationship between technology and health care spending growth. Although blockbuster technologies undoubtedly bring substantial benefits to patients, spending may increase because they broaden the definition of health care and command high prices. While ambulatory care may be a more cost-effective mode of delivery, the shift to this new site of care has required a substantial investment in new infrastructure and has increased demand for treatments that previously might have been foregone because they required hospitalization.

Medicare Managed Care. We did not find evidence of an important independent effect of Medicare managed care among either MCOs or manufacturers. MCOs generally set uniform coverage policies for their Medicare and commercial products, although there is occasionally a divergence when Medicare FFS policy conflicts with the plan's internally developed guidelines. Manufacturers similarly acknowledged that Medicare managed care is indistinguishable from commercial managed care. In addition, enrollment in Medicare+Choice plans has not reached a high enough level to engage their attention and manufacturers expressed skepticism about the likelihood of substantial long-run growth in Medicare managed care penetration. Finally, provider adoption decisions are influenced more by their mode of reimbursement than by manager per se. Moving commercially-insured patients from traditional indemnity insurance to managed care may substantially alter hospital incentives by changing the mode of reimbursement from FFS to some form of bundled payment. In contrast, transitioning Medicare patients from FFS to Medicare+Choice does not fundamentally change hospital incentives because they already receive bundled payment under FFS Medicare. Indeed, to the extent that they are able to negotiate FFS reimbursement or per diem payments, which may be considered less bundled than DRGs, hospital incentives to adopt cost-reducing technologies may be less under Medicare+Choice than under FFS Medicare.

Conclusion

While managed care plans do attempt to control use of certain technologies, their ability to do so is more restricted than expected. Similarly, managed care undoubtedly influences manufacturer R&D investment decisions through their coverage and payment policies. However, it is not clear that it has changed the likelihood that cost-increasing technologies will come to market, nor has it altered the fundamental feedback relationship between insurance, technological innovation, and health care expenditure growth.

It is important to recognize that our study was conducted under a particular set of economic conditions that may have exerted a significant impact on our findings. In many markets, insurers have kept premium increases low (perhaps artificially so) for several years. In the present robust economy, employers use generous benefits to compete in tight labor markets. As a result, managed care plans are being pressured to adopt less, not more, restrictive coverage policies. In the end, patient willingness to pay, whether through greater cost sharing or higher insurance premiums, will determine the rate of technology diffusion. Currently, it appears that the will to pay remains strong. However, these findings could certainly change with a return to double-digit premium increases or an economic downturn.

1 Introduction

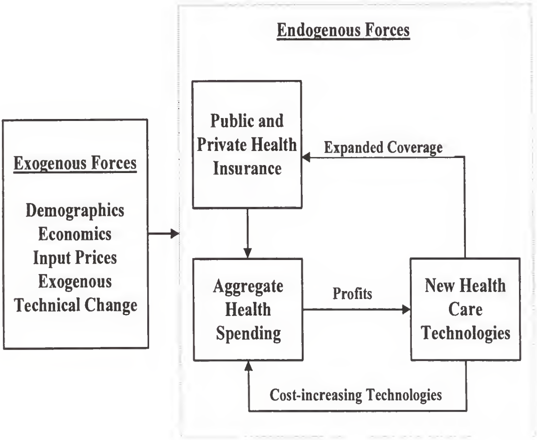
1.1 Conceptual Model

The ever-increasing trajectory of health care spending in the United States has been an ongoing concern of analysts and policymakers for more than two decades. Between 1960 and 1993, real per capita spending nearly quintupled, growing by 373 percent (Peden and Freeland, 1998). A variety of forces have been posited as drivers of this cost growth, including the aging of the population, the increase in per capita income, the increase in insurance coverage, and the increased supply of physicians (Newhouse, 1993). The contribution of technological innovation to this cost growth has drawn increasing attention. Although difficult to quantify, many analysts have identified the development and adoption of new technologies as a primary force behind rising health care expenditures (Cromwell and Beaven, 1994; Newhouse, 1993; Peden and Freeland, 1998).

Technology plays a complex role in driving health care spending because of its interactive relationship with health insurance. Figure 1-1 illustrates key factors that determine health care spending levels. These factors can be separated into two broad categories: exogenous forces and endogenous forces. Exogenous forces include underlying demand and supply factors that determine health care expenditures. Demand side forces include the demographics and wealth of the population. On the supply side, input prices driven by general economic conditions affect the cost of providing services and, hence,

Figure 1-1

Interaction of Technology, Insurance and Health Care Spending


Endogenous Forces
Exogenous Forces
Demographics
Economics
Input Prices
Exogenous
Technical Change
Public and Private Health Insurance
Expanded Coverage
Aggregate Health Spending
Profits
New Health Care Technologies
Cost-increasing Technologies

spending. The supply influenced by technological changes that occur outside of the health care industry, such as the development of computers and fiberoptics.

However, many of the important determinants of health care spending can be viewed as endogenous to the health care system. These factors are of particular interest to policymakers because unlike changing population demographics, for example, they are potentially amenable to interventions that would contain spending growth. These endogenous forces illustrate the interactive role played by health insurance and technology research and development (R&D) in driving up the costs of health care (Weisbrod, 1991). Beginning with expanded private coverage after World War II and followed by the introduction of Medicare and Medicaid in the 1960s, growth in health insurance has increased the demand for health care and aggregate spending. As insurance increases spending on health care, profits are generated that encourage investment in R&D on new technologies. The introduction of new drugs, devices, and other technologies affects spending in two ways. First, historically most technologies have been cost-increasing and, thus, directly raise aggregate health spending. New technologies have an additional, indirect effect on health care spending via their impact on the demand for insurance. As new technologies come on-line, the definition of insurance expands to cover them which, in turn, increases consumer demand for services. This feedback loop between health insurance and technological innovation contributes to spiraling health care expenditures.

It has been suggested that managed care has the potential to break this spiral by altering this feedback loop (Weisbrod, 1991). First, managed care is expected to reduce the level of health care spending relative to indemnity insurance by controlling utilization and, perhaps, provider fees. While the ability of managed care to reduce the level of health care spending relative to indemnity insurance is fairly well recognized (Miller and Luft, 1994), its ability to reduce the rate of spending growth depends on changes at several other points in the loop. Managed care plans may be less likely than traditional indemnity plans to cover new technologies or may be better able to control the diffusion of those that are covered. Thus, the tendency of insurance coverage to expand as technologies are introduced is mitigated. Managed care plans are expected to particularly control the adoption of cost-increasing technologies. As the importance of managed care grows, incentives for R&D investment may shift away from technologies that increase costs without a commensurate improvement in outcomes to those that can demonstrate cost-effectiveness or even reduce costs. The impact of managed care on profits is less certain. For example, greater use of formularies, generic substitution, and negotiated discounts by managed care organizations (MCOs) have a negative effect on pharmaceutical industry profits. On the other hand, research has indicated that enrollees in MCOs use prescription drugs at a higher rate than those in indemnity plans (Weiner *et al.*, 1991). This increased demand would have a positive effect on industry profits.

Evidence as to whether managed care can reduce the rate of health care spending growth and control adoption of technology is decidedly mixed (Chernew *et al.*, 1998). However, there are a number of reasons why the hypothesized reduction in spending growth has not been observed in the past. First, until fairly recently, managed care penetration rates were relatively low in most markets. As long as indemnity plans remained the dominant form of insurance, MCOs could compete for enrollees by setting their premiums just below those of indemnity insurers. With this "shadow pricing", MCOs could compete simply by reducing hospitalization rates or negotiating discounts, and it was not necessary to control the use of technology. Second, many technology adoption decisions are not within the direct purview of MCOs. Rather, they are made by hospitals and physicians, who use new technologies to compete for patients. Third, MCOs use access to technology as a signal of quality and a means of competing for enrollees.

However, this may change as the importance of managed care in the health insurance market grows. MCOs increasingly compete head-to-head, rather than with indemnity insurers. This competition forces MCOs to make more fundamental changes in service delivery patterns. In addition, even indemnity insurers now seek to manage utilization and may no longer provide unfettered access to new technologies. The growth in Medicare managed care is particularly significant given the size of this population and its high levels of service use.

On the other hand, countervailing forces may still limit the impact of managed care on technology and health care spending. Recent years have seen a backlash against the managed care industry and a growing public perception that treatment decisions may be motivated more by financial considerations than by the best interests of the patients. The news media is replete with stories about patients with life-threatening conditions who have been denied coverage of potentially life-saving treatments by bean-counting managed care plans. This distrust has produced a groundswell of interest in Patients' Bill of Rights legislation that, if enacted, could limit the ability of MCOs to control access. In addition, the managed care market has shifted from traditional group and staff model plans, which have been shown to be more effective at controlling costs, to IPA and other open panel plans. Far from pressuring managed care plans to restrict access to costly therapies, bolstered by a strong economy, consumers and purchasers are demanding more generous benefits and freedom of choice.

The purpose of this study was to explore the hypothesis that managed care can break the spiral in health care expenditures by managing the use of technology and by changing the incentives of manufacturers to bring new technologies to market. Our goal was to go inside the black box of decision making at MCOs and manufacturers of health care technology in order to understand how managed care affects the adoption and development of technologies and how this might change in the future as enrollment in managed care grows. Our study is not designed to test empirically the impact of managed care on the use of technology and the direction of health care R&D. Rather, by focusing on the decision-making process, we sought to illuminate the myriad forces that shape of ability of managed care to influence the use and development of health care technology and to see whether they are consistent with predictions in the literature.

1.2 Overview of Study Design

In this study, our definition of technology encompassed procedures, devices, and pharmaceuticals, including biotechnology. We adopted a two-pronged approach to studying the impact of managed care on the adoption and development of new technology, looking at both the demand side (MCOs) and the supply side (manufacturers of health care technology). We gathered information on MCO and manufacturer decision-making through case study interviews. Although the generalizability of case study results is limited by the small number of sites covered, case studies are well-suited to in-depth exploration of complex issues such as those addressed in this report.

On the demand side, our case studies examined how MCOs make decisions about the coverage of specific technologies and the factors influencing those decisions. We also conducted interviews at selected hospitals and large physician groups because many important technology adoption decisions are not made directly by MCOs. Rather, the influence of managed care may be observed indirectly via its impact on hospital technology adoption decisions and on coverage decisions by physician groups to which MCOs have off-loaded high levels of risk. In addition, we spoke with representatives at three types of outside organizations that are of growing importance for MCO technology coverage decisions--technology assessment organizations, pharmacy benefits managers (PBMs), and external review organizations. Rather than conducting their own technology assessments, which can be costly and time-consuming, many MCOs rely on assessments from outside vendors such as technology assessment organizations and PBMs. While these organizations do not make coverage decisions per se, their reviews of new technologies are a key component of the plan decision making process. Either through voluntary action or legislative mandate, MCO coverage decisions increasingly are subject to external review by organizations intended to provide an impartial, third-party venue for appeals. External review may constrain the ability of MCOs to limit technology coverage, either by overturning coverage decisions or by influencing the willingness of plans to write restrictive policies.

Our MCO case studies also addressed how plans make decisions about benefit package design and beneficiary cost sharing requirements. While coverage decisions represent a direct response to the introduction of new technologies, plans may also respond by using features of their product offerings to control or to accommodate rising costs associated with new technologies. For example, plans may trade off higher beneficiary copayments or premiums for more generous coverage policies. Alternatively, they may elect to exclude entire classes of high cost services or to offer them as options to purchasers. MCOs often offer customized products to large purchasers , who may play a significant role in benefit design decisions.

The MCO case studies targeted plans in selected market areas because we hypothesized that coverage decision-making might vary by the maturity and competitiveness of the managed care market. Therefore, we identified markets with differing levels of managed care penetration. Within markets, we contacted MCOs with varying characteristics (e.g., size, age, organizational type, market share) to capture the range of responses to market conditions. Because we had a particular interest in the impact of growth in Medicare managed care, nearly all of the MCOs visited were Medicare + Choice plans. In addition to conducting interviews at local plan affiliates, we also spoke with representatives from the headquarters of selected national plans.

Our supply side case studies focused on R&D investment decisions made by the manufacturers of health care technology. We selected manufacturers of technologies with characteristics that varied along dimensions that were expected to impact the influence of managed care. Our study included both device manufacturers and pharmaceutical companies. We expected that effects of managed care might be felt differently across these industries. Managed care plans are direct purchasers of pharmaceuticals; decisions to purchase devices, although influenced by plan payment and coverage policies, are made by providers that are only rarely under the direct control of managed care plans. In addition, past research indicates that managed care has a positive impact on the overall demand for pharmaceuticals.

Our interviews addressed the full range of factors expected to drive manufacturers R&D agendas. These included forces exogenous to the health care industry, as well as endogenous forces. Among the exogenous forces were scientific advances, population demographics, and patterns of illness. The endogenous forces included managed care generally, Medicare managed care in specific, and Medicare fee-for-service payment policies. We also discussed manufacturer marketing strategies and the extent to which they use forecasting to guide R&D investment decisions.

We have been guided throughout this study by a Technical Advisory Group (TAG) of experts on the managed care, pharmaceutical, and device industries. The TAG provided consultation on the design of the case studies, including the development of interview protocols, selection of interview sites, and the selection of tracer technologies used to focus our interviews. The TAG was composed of the following experts:

- Managed Care: Robert Hurley, Ph.D., Associate Professor, Medical College of Virginia.

- Pharmaceutical Manufacturers: Alison Keith, Ph.D., Director of Economic Policy Analysis, Pfizer, Inc.
- Device Manufacturers: Robert Moliter, Managing Director, Strategies for Technology; retired Director of Government and Industry Relations for GE Medical Systems Group.

1.3 Organization of the Report

The remainder of this report is organized as follows. Chapter 2 reviews the literature related to managed care, technology, and health care spending. Chapter 3 describes the methods used in our case studies of MCO and manufacturer decision making. Chapter 4 summarizes findings on MCO coverage decision making, while Chapter 5 discusses plan benefit and cost sharing design. Chapter 6 reviews the results of our case studies of device manufacturers. Findings for pharmaceutical manufacturers are presented in Chapter 7. The final chapter synthesizes the findings from our MCO and manufacturer case studies and discusses their implications for nine hypotheses drawn from the literature. We conclude by raising questions that remain unanswered and propose directions for future research.

2

Literature Review

This chapter reviews the literature in four areas related to our study of the impact of growth in managed care on the adoption and development of new technologies and its implications for future health care spending growth. As described in the previous chapter, there is a complex, interdependent relationship between health insurance, the adoption of technologies, the direction of technological innovation, and health care expenditure growth. It has been hypothesized that managed care may alter these relationships in ways that will change the trajectory of spending growth.

This literature review describes what we know about the set of relationships in this equation. First, we survey research that examines the effect of managed care on growth in health care expenditures. Next, we look at the contribution of technology to spending growth. The third section reviews evidence on the impact of managed care on the adoption and diffusion of technologies. Our literature review concludes with an examination of literature on the implications of managed care for research and development of new technologies.

2.1 Impact of Managed Care on Health Care Spending Growth

In contrast to FFS indemnity insurance, which encourages providers to maximize the quantity of services provided, managed care is expected to reduce the level of health care spending by creating incentives for providers to limit the cost of services. MCOs use a variety of mechanisms to reduce expenditures, including negotiating discounts with providers, monitoring service use, instituting financial incentives for providers to restrict service delivery, encouraging provision of preventive and primary care services, and contracting with providers that have conservative practice styles. In this section, we first discuss the literature on the impact of managed care on expenditure levels and then summarize findings regarding the impact on expenditure growth.

There is an extensive literature stretching over several decades that compares the level of health spending under managed care to indemnity insurance. Miller and Luft (1994) summarized the evidence on the relative performance of managed care and indemnity plans. The studies included in their review confirm that total expenditures are lower under managed care compared to FFS insurance. MCOs mainly achieve these savings by reducing utilization of hospital services. Even after adjusting for differences in the characteristics of enrolled populations, MCOs have lower admission rates, shorter lengths of stay, and fewer inpatient days than FFS plans. Enrollees in MCOs also had fewer mental health visits. In addition, MCOs were found to provide fewer services that are expensive or have lower cost alternatives, suggesting that one of the ways in which MCOs reduce spending is by limiting the adoption of costly technologies. On the other hand, the studies reviewed showed that MCOs had an office visit rate that was similar to or greater than that in indemnity plans and findings were mixed with respect to the impact on physician and outpatient charges.

However, given the dynamic and rapidly evolving nature of MCOs and the health care market generally, the studies reviewed may not reflect current market conditions.

One of the ways in which MCOs are expected to reduce utilization is by changing the financial incentives for physicians to provide services. Hellinger (1996) reviewed the literature comparing physician behavior under the financial incentives of managed care to behavior under FFS and concluded that these incentives are a key factor in explaining physician decisions regarding service delivery. Hellinger cautioned that most of the studies were limited in their ability to measure the impact of financial incentives because they did not adequately control for enrollee, physician, plan, and market area characteristics that might affect utilization. However, the consistency of findings across studies suggests that financial incentives are a major contributor to lower utilization rates under managed care.

Although lower utilization should be reflected in lower insurance premiums, Miller and Luft (1994) note that there is no peer-reviewed literature comparing premiums in MCOs with FFS plans that adjust for enrollee and plan differences, such as enrollee age, number of dependents, sex, health status, benefit package, and location. Analysts have speculated that in markets where FFS is the dominant form of insurance, MCOs have adopted a strategy of "shadow-pricing", i.e., setting their premiums just below those of indemnity plans. But, as managed care becomes increasingly important and markets grow more competitive, this strategy may no longer prevail. Wholey and colleagues (1995) examined the impact of market structure on premiums for managed care plans and found that premiums were lower in more competitive markets, defined as those with more plans and a higher managed care penetration rate. However, the effect of market structure differed for IPA and group-model plans. For group-model plans, both the number of plans in the market and the penetration rate had negative effects on premiums, while penetration had an impact on IPA rates, but only in areas with the highest number of managed care plans. At all levels of market competition, the impact on IPA premiums was less than that on group-model plans.

Another study that examined the impact of market competition on expenditure levels, looked at the effect of managed care market share on hospital expenditures (McLauglin, 1988). While areas with high managed care penetration rates had higher mean expenditures, there were no differences associated with market share after controlling for simultaneity in the relationship between managed care market share and hospital costs. Because MCOs have tended to locate in markets with high hospital costs, studies that do not adjust for these selection effects will produce biased estimates of MCO market share effects. The data in this study (from 1980) are now quite dated, however, and are unlikely to reflect current market conditions. Most significantly, prepaid group practices were the main model type at that time, whereas IPAs have subsequently emerged as the dominant form of MCO. Group model plans, which may operate their own hospital rather than contracting with community hospitals, would be expected to have less of an impact on market-level hospital costs than IPAs.

Lower expenditure levels in MCOs do not necessarily imply lower growth rates. If, as the literature suggests, the main impact of MCOs is a reduction in hospitalization rates, this implies a downward shift in costs with a move to managed care, but not a change in the rate of increase unless relative hospitalization rates in managed care and FFS plans change over time or relative costliness changes in other ways. This might happen if, for example, MCOs adopt new technology at a lower rate than indemnity plans (Newhouse, 1993, Newhouse *et al.*, 1985).

In their review of the literature on the impact of managed care on health care expenditure growth, Chernew and colleagues (1998) classified the research in this area into two broad categories: "horse race" approaches and "market comparison" approaches. Horse race studies compare growth in spending between managed and unmanaged (or less strongly managed) plans. Market comparison studies contrast growth rates in areas with differing managed care penetration rates. While horse race studies generally show that cost growth is no different in managed and unmanaged plans, market comparison studies show lower rates of spending growth in areas with higher managed care penetration (see, for example Gaskin and Hadley, 1997; Cutler and Sheiner, 1997). On the other hand, findings from a study confined to the Madison, Wisconsin market area by Hill and Wolfe (1997) diverged from other market comparison studies. The authors found lower premium growth in the first two years after a rapid increase in managed care activity. Afterward, however, growth rates returned to national levels. A national study, which used data from 1982 to 1996 to compare changes in hospital expenditures and utilization across MSAs, found only small growth differences between high and low penetration markets—generally less than 1 percent annually depending on the specific measure (Anderson *et al.*, 1999).

Chernew *et al.* (1998) reconcile the disparate conclusions drawn from horse race and market comparison studies by positing that there are significant spillover effects from managed care to the FFS sector. If the existence of MCOs lowers costs for non-MCOs, this could produce lower cost growth in market areas with high managed care penetration rates. The authors suggest that spillover effects might occur if: (1) indemnity plans are able to take advantage of the same discounts as managed care plans; (2) physicians operate in both sectors and treat all patients the same, regardless of type of insurance; or (3) managed care produces a shift in the resources available to deliver care. On the other hand, reductions in cost growth observed in market-level studies may simply be transitional if they reflect, for example, movement to increasingly strict forms of managed care with lower cost levels. Unless these plans have a lower rate of growth compared to other forms of insurance, lower rates of growth in high penetration areas would not be sustained in equilibrium. A related explanation, not posed by the authors, is that areas with high managed care penetration have higher rates of growth in managed care enrollment. Areas that shift more people into managed care plans over time will also experience lower average growth rates by virtue of the fact that MCOs have lower expenditure levels. However, when an equilibrium level of managed care penetration is reached, growth rates in high penetration markets would return to the same level as those in low penetration areas.

2.2 Impact of Technology on Health Care Spending Growth

The past thirty years since the introduction of Medicare and Medicaid health insurance coverage for the elderly and poor has witnessed an extraordinary increase in national spending on health services. Many researchers (Newhouse, 1993; Peden and Freeland, 1998; Weisbrod, 1991; Cromwell and Beaven, 1994; Ashby and Lisk, 1992) have attempted to explain the sources of growth and HCFA's Office of the Actuary (Arnett *et al.*, 1985; Burner, Waldo, and McKusick, 1992; Levit *et al.*, 1996) has monitored spending and the underlying drivers of higher costs.

There is general agreement in the literature that technical innovations in medicine have been a principal cause of higher spending. Factors such as population growth, the increased aging of the population, and higher real incomes explain only a small portion of the growth (Newhouse, 1993; Peden and Freeland, 1998). Economists and actuaries have identified the rapid decline in the proportion of health care bills paid for by patients at point-of-purchase as another dominant causal factor in greater health spending. The general argument is that lower net prices to patients—especially the elderly and the poor—have encouraged health care providers to diagnose and treat patients more intensively, almost without regard to cost. Insurer payment systems reinforced provider incentives by paying primarily on a cost-incurred basis. While providers could have responded by providing more of the same kinds of services (e.g., more hospitalizations), they opted to provide far more intensive care for existing illnesses, as well as to seek ways of treating chronic and previously untreatable illnesses. The literature also emphasizes the role of public funding for basic and applied scientific medical research as a further enabler of innovative, costly medical technologies (Peden and Freeland, 1998).

Another facet of technology innovation raised in the literature is the ability of new devices and drugs to broaden the basic definition of health care (Weisbrod, 1991). In vitro fertilization and the impotence drug, Viagra, improve the quality of life and are increasingly demanded by patients to be covered under insurance plans.

Two strains of literature either question the relative importance of technology in spending growth (Cromwell and Beaven, 1994) or its implications for consumer welfare (Ramsey and Pauly, 1997; Boutwell and Mitchell, 1993; Trajtenberg, 1990). Programmatic changes in payment policies have undoubtedly played a major role in the upsurge in health spending, especially at certain key times such as the mid-1960s with the introduction of Medicare and Medicaid. Utilization and spending have risen dramatically in a few sectors where technology is not thought to play a major role, e.g., nursing homes, mental hospitals, non-physician clinical professionals (e.g., psychologists, physical therapists) (unpublished HCFA data in Cromwell and Beaven, 1994). It is admittedly difficult to isolate the independent role of technology from the general expansion of coverage and the growth of complementary health care services. The problem may be definitional. If new technologies prolong life (e.g., revascularization, dialysis), should the rather non-technological nursing home care that accompanies old age be considered "technology driven"? Indeed, is it even possible to classify nursing home admissions into those that derive from technological progress and those simply from increasing infirmities of old age?

A second strain of literature points out that greater health care spending due to outward shifts in demand because of innovative technologies may raise consumer welfare and be well worth the cost. Open heart surgery and dialysis have added billions of dollars of spending each year, not counting complementary health care spending. Is this spending increase a concern to policy makers? Assuming the answer is yes, is it inefficiently provided in any sense? Whatever the answers to these questions, it seems clear that technologically driven increases in health care spending that shift out the boundaries of health treatment are more justifiable than spending with little or no health improvement.

Two conclusions can be drawn from such arguments. First, isolating the contribution of innovative technologies to spending is valuable in rationalizing the spiraling health care costs to Americans. Second, gaining a better understanding of how managed care organizations evaluate the cost effectiveness of new technologies is critical to projecting, not only future spending, but future gains in consumer welfare as well. At the very least, price increases in Medicare that are adjusted to hold constant the level of quality are certainly far less than those standardly reported by the Bureau of Labor Statistics (Trajtenberg, 1990; Cleeton, Goepfrich, and Weisbrod, 1992; Triplett, 1999).

2.3 Impact of Managed Care on the Adoption of Technologies

Given the important role technology is believed to play in driving health care expenditure growth, the ability of managed care to control the adoption and diffusion of technologies will be a critical determinant of its impact on long-term trends in spending.

Weisbrod (1991) hypothesized that managed care plans will be less likely to adopt cost-increasing technologies than indemnity plans. Chernew *et al.* (1998) note, however, that a slower rate of technology diffusion under managed care does not necessarily imply lower rates of health care cost growth. If the current level of technology use is lower in MCOs, then not only must they adopt new technologies at a lower rate, but the relative use of new technologies must be lower in managed care compared to FFS than the relative use of existing technologies. Moreover, many important technology adoption decisions are not made directly by MCOs, but rather by providers such as hospitals. Griner (1991) contends that managed care will not slow the adoption of new technologies because they are critical to the ability of hospitals to compete for contracts, which becomes increasingly important as managed care grows.

Several theory papers have examined the factors that may lead to differences in technology adoption and the types of technology for which differences are likely to be observed. Baumgardner (1991) developed a theoretical model of the welfare implications of new technology under conventional FFS insurance and managed care. MCOs and FFS plans are distinguished by the tools available to control utilization. While FFS plans rely on copayments as a broad tool to control use, MCOs can set treatment levels for patients within an illness category. As a result, the welfare effects of technical change depend on the form of insurance. Baumgardner's theory implies that technologies that shift the boundary of care (i.e., change the health-improving value of extra care) are more likely to induce welfare loss under conventional insurance because the insurer cannot control utilization by less severely ill patients. On the other hand, technologies that reduce nonpecuniary costs (e.g., a reduction in the riskiness or pain of a procedure) are more likely to lead to welfare loss in MCOs because patient demand is not constrained by copayments. Ramsey and Pauly (1997) criticized Baumgardner's conclusion that MCOs are more effective at controlling the adoption of technology and avoiding welfare loss associated with technical change. They contend that his finding is dependent on the assumption that FFS insurers cannot refuse to reimburse new technology whereas, in fact, they may not cover all new technologies. If this assumption is changed, they find that MCOs will sometimes adopt costly technologies that FFS plans will not adopt.

Chernew *et al.* (1998) reviewed four studies on the relationship between managed care and the adoption and diffusion of new technologies. They find mixed evidence that managed care controls technology diffusion. Three studies found no relationship between the type of insurance and utilization trends following the introduction of a new technology (see also Ramsey *et al.*, 1997). One study showed that patients in markets with high levels of managed care penetration were less likely to undergo angioplasty and hospitals in high penetration markets adopted this technology at a slower rate. The latter finding is consistent with, though not necessarily associated with, slower growth in utilization of angioplasty in high penetration markets. Cutler and Sheiner (1997) also found a negative correlation between managed care penetration and technology growth, but only after controlling for the baseline diffusion rate. On the other hand, Chernew *et al.* (1997) found evidence in some markets of higher growth rates for laparoscopic cholecystectomy in managed care plans compared to the general population. Because this is a less invasive alternative to previous treatment options, the finding is consistent with Baumgardner's hypothesis that MCOs will find it hard to control utilization of technologies that reduce non-pecuniary costs to the patient.

While these studies look at utilization rates as a manifestation of technology adoption, others have looked more directly at adoption and coverage decisions. Using an index that measures the availability of a range of hospital technologies as an indicator of technology growth rates, Baker and Spetz (1998) found some evidence of a negative relationship between managed care market share and technology adoption in the early and mid 1980s, but not in later years. However, managed care effects varied by individual technology. Steiner and colleagues (1997) found that managed care plans were less likely to cover a variety of laser therapies than indemnity plans. A survey of physicians on the adoption of laparoscopic cholecystectomy showed that surgeons with a high proportion of FFS revenue adopted this technology earlier than those who were less reliant on FFS reimbursement (Escarce *et al.*, 1995). In addition, physicians with a moderate proportion of their patients in managed care adopted earlier than those with a low or high proportion. Although this is a cost-reducing technology that was expected to be adopted earlier in MCOs, the authors note that physicians with the highest proportion of patients in managed care are probably more likely to be in staff model plans. These physicians do not have an incentive to adopt technologies in order to compete for patients. Furthermore, recognizing the difficulty in constraining patient demand predicted by Baumgardner, MCOs may have discouraged adoption of this technology. Evidence on the relationship between managed care penetration and the decision of providers to invest in costly new technologies (e.g., MRI and hospital-based technologies) is mixed (Baker and Wheeler, 1998; Hill and Wolfe, 1997).

The implications of managed care for prescription drug use is somewhat different than other technologies. Enrollees in managed care plans had higher rates of prescription drug use than those in indemnity plans, although annual prescription costs were similar or slightly lower in MCOs due to lower unit costs and the use of generic substitutes (Weiner *et al.*, 1991). However, the authors found no evidence that managed care plans restricted access to innovative products. This suggests that managed care will not discourage R&D of innovative drugs. Although greater use of generics reduces the returns to R&D, this is offset by higher overall use of pharmaceuticals under managed care.

Several studies have explored the procedures used by MCOs to make coverage decisions and the factors influencing these decisions. Rettig (1997) describes the technology assessment activities of a variety organizations, including a number of MCOs. While the Blue Cross Blue Shield Association has a long-standing technology assessment program, national insurers and MCOs such as Aetna, Harvard Community Health Plan (now Harvard Pilgrim Health Care), Kaiser, Prudential, and United Health Care have developed these capabilities more recently as a way to guide coverage decision making.

A survey of insurance plan medical directors found that coverage decisions for three laser therapies (laser angioplasty, laser discectomy, and photodynamic therapy for bladder cancer) were mainly determined based on clinical efficacy, cost-effectiveness, and FDA approval (Steiner *et al.*, 1997). However, MCOs were more likely than indemnity plans to cite the potential for reducing costs as a reason for covering angioplasty. Furthermore, larger plans were less motivated by concerns about competitors' coverage decisions than were smaller plans. A companion article (Steiner *et al.*, 1996) reported that medical directors are usually involved in coverage decisions, but only had final authority in approximately one-quarter of the insurance plans. A third article based on this survey (Powe *et al.*, 1996) showed that plans are generally unaware of whether providers are using the three laser therapies noted above. MCOs were more likely than indemnity plans to be aware of the procedures providers used, but the difference was only significant for angioplasty. The inability of insurers to monitor utilization of technology suggests that it may be difficult for them to control its use.

Articles by Luce and colleagues describe technology assessment procedures in hospitals, MCOs, and MCO pharmacies. Case study interviews with managed care plans, hospitals, and third-party payers (Luce and Brown, 1995) found that technology assessments undertaken by MCOs tend to be focused on outcomes such as safety and clinical effectiveness, while hospital assessments focus on financial feasibility. With the exception of formulary committees, financial analyses tend to focus on immediate costs of adoption and not the long-run impact on practice patterns. MCOs generally make coverage decisions at the regional level, while equipment purchases are assessed at the plan level. MCOs typically conduct technology assessments for new, expensive, or controversial procedures, although final coverage decisions take into account implications for premiums and competition.

MCOs also conduct assessments for the purchase of expensive or controversial equipment. Hospitals always undertake a centralized assessment before making purchase decisions for high-cost new technologies, while lower cost purchases are assessed at the department level. A survey of pharmacy directors at 51 MCOs (Luce *et al.*, 1996) found that all plans have formularies, but they vary in their degree restrictiveness. Economic considerations were reported to influence formulary decisions in nearly all plans. More than half of the plans assess the majority of new drugs that come on the market and a small number contracted pharmaceutical assessment to pharmacy benefit managers (PBMs).

A recent study (Titlow *et al.*, 2000) reported on MCO coverage decisions and factors influencing those decisions for four new costly medications (Viagra, for treatment of impotence; Zyban, for smoking cessation; Enbrel, for treatment of rheumatoid arthritis; and Celebrex, a Cox-2 inhibitor for relief of arthritis symptoms). The survey of 53 MCOs showed that Enbrel and Celebrex were more likely to be covered than Viagra and Zyban, which were perceived to be "lifestyle" drugs. More than 90 percent of the respondents covered Enbrel and Celebrex, while 72 percent covered Viagra and only 49 percent covered Zyban. Among those MCOs covering these drugs, the vast majority applied some restrictions to their use. Approximately one-fifth covered Enbrel and Celebrex without limitation, while Viagra and Zyban were almost always subject to some limit. Viagra and Zyban were most likely to be limited through restrictions on quantity or duration of use, as well as overall exclusion of a class of drugs or treatments for a specific condition (i.e., sexual dysfunction and smoking). Indeed, 8 percent reported making sexual dysfunction a contractual exclusion after Viagra was introduced. Enbrel and Celebrex were most likely to be limited by requiring prior authorization. However, several respondents had discontinued prior authorization for Viagra, Zyban, and Celebrex because of the high administrative costs relative to savings from decreased use. While just under half of the MCOs reported that cost was among the top five determinants of their coverage decision, safety and FDA approval were the factors cited most often.

2.4 Impact of Managed Care on Research and Development Investment Decisions

Practically no literature exists on the empirical link between managed care and manufacturer R&D decisions. A few qualitative articles speculate on the role payment systems have more generally on investment decision making (Weisbrod, 1991; Holmes, 1991; Kahn, 1991; Telling, 1991; Griner, 1991). There is a general consensus that changes in payment methods do filter back to manufacturers, but little is known about managed care impacts per se. The introduction of cost-based Medicare and Medicaid insurance systems is believed to have stimulated the interest in new medical devices and drugs beginning in the mid-1960s (Holmes, 1991). Both the much lower cost to patients at point-of-service and the cost-based nature of reimbursement contributed to the burgeoning opportunities to adapt non-medical technologies (e.g., computers, lasers, fiberoptics) to health care.

The literature suggests these incentives changed dramatically in the mid-1980s with the introduction of Medicare per discharge hospital prospective payment (Cromwell and

Beaven, 1994; Holmes, 1991; ProPAC, 1986). In particular, incentives were introduced to develop new devices and drugs that shortened inpatient stays and permitted more care on an outpatient basis, which remained cost-based for the most part. Problems with orphan devices and drugs also arose (ProPAC, 1986). Some conditions may be so rare that, given the new financial constraints on reimbursement, certain products would not be available to needy patients (e.g., cochlear implants).

Moreover, technologies that would certainly have remained inside the hospital now, under prospective payment, were being adapted to an ambulatory setting. MRI and CT scan clinics were established, lithotripers were put on 18-wheel trucks, and ultrasound machines were being downsized for practitioners' offices. Ambulatory surgery using endoscopes was yet another industry response to the changing incentives.

Very little mention is made of managed care and R&D decision making in the literature prior to the 1990s. A limited literature is now appearing on how R&D firms may be responding to the growth in managed care (Dranove and Weisbrod, 1997; Griner, 1991; Telling, 1991). (As described in the previous section, a much larger literature exists on the intermediate link involving MCO decision making regarding coverage and access to new technologies.) Experts speculate (Telling, 1991) and MCO managers report (Dranove and Weisbrod, 1997) that R&D firms are shifting their drug and device portfolios towards more innovative products, rather than marginal improvements on existing technologies. The greater financial risk if such a shift is also noted. Particular concern has been voiced over the managed care plan's gatekeeper role concerning drugs and the drive for cost reduction at the expense of patient welfare (Telling, 1991). Some have hypothesized that managed care may have lesser impact on device innovation to the extent that innovation is lodged in small "cottage" firms that are far removed from considerations of the ultimate market (Kahn, 1991). Many small firms simply hope to be bought out by larger firms who then must worry about marketing to managed care.

Two responses reported by R&D firms are noteworthy. First, R&D firms will be designing therapeutic substitutes that reduce costs (Dranove and Weisbrod, 1997). Second, firms will also be developing wholly new products without substitutes that effectively expand the boundaries of health care (Dranove and Weisbrod, 1997). By driving R&D firms to place increasing emphasis on major innovations, which payers will have no choice but to cover and which can command high prices, managed care may have the unintended effect of fueling increases in total health spending (Weisbrod and LaMay, 1999).

Over the last 30 years a phenomenal R&D infrastructure has been fostered, in part, by the growth in insurance coverage. This wealth of resources is well suited to simultaneously meeting the short-run cost containment goals of managed care plans, while "forcing" the plans to expand coverage for radically new devices and drugs that enhance the quality of life. While policy changes, such as the introduction of prospective payment in the 1980s, may produce a temporary pause in the adoption of new technology, providers have adapted to these changes so that they have not arrested long-run trends in the overall cost of new technologies. If nothing else, managed care faces significant hurdles in trying to alter R&D decisions through coverage and access protocols.

2.5 Study Hypotheses

Our case study interviews sought to address nine key hypotheses derived from the literature. These hypotheses are as follows:

Hypothesis #1: Managed care plans are less likely to cover costly new technologies and more likely to restrict access to them than fee-for-service plans.

Hypothesis #2: Medicare managed care reinforces private managed care in slowing the development and diffusion of new, cost-increasing medical technologies.

Hypothesis #3: Managed care plans limit utilization by rationing quantities, while fee-for-service insurers rely on cost sharing.

Hypothesis #4: Managed care plans engage in rigorous cost effectiveness studies of new technologies in their coverage decisions.

Hypothesis #5: Medical care manufacturers mold their R&D spending to changes in insurer methods of payment and managed care.

Hypothesis #6: Managed care restricts the diffusion of new technologies by molding the adoption decisions of providers.

Hypothesis #7: Both managed care plans and providers use new technologies to compete for subscribers and patients, which, in turn, supports new technology development among manufacturers.

Hypothesis #8: Access to costly technologies is more restricted in markets where there is greater competition between managed care plans.

Hypothesis #9: Population growth, the aging of the population, and higher incomes explain only a small portion of the growth in health spending and, by extension, R&D spending on new technologies.

The final chapter of this report synthesizes our findings with respect to these central hypotheses.

3

Case Studies Methods

3.1 Managed Care Organizations

3.1.1 Introduction

This section describes the methods used in our case studies of MCO decision making regarding coverage of new technologies and the design of product offerings. We conducted interviews with 18 MCOs in six market areas across the country. The section begins with a discussion of the selection of interview sites, including market areas and plans within those areas. In addition to interviewing managed care plans, we met with hospitals and large physician groups, both of which play a direct role in the adoption and use of new technologies and whose decisions may be influenced by managed care. While most interviews with MCOs were conducted in local market areas, we also met with staff from the national headquarters of selected plans. Additional interviews were conducted with three types of organizations that have a collateral role in MCO coverage decision making—technology assessment organizations, pharmacy benefits managers (PBMs), and external review organizations. Virtually all MCOs rely to varying degrees on reports prepared by technology assessment organizations in making their coverage decisions for devices and procedures. PBMs, which some MCOs use to set their formulary, provide an analogous function with respect to drugs. Whether through voluntary efforts or legislative mandate, coverage decisions by managed care plans increasingly are subject to appeal to external review organizations. We interviewed representatives from both technology assessment and external review organizations to learn about the processes they use and their potential impact on technology coverage decisions by MCOs.

The next section summarizes the topics covered in our interviews, including questions related to coverage decision making and benefit design. We then provide overviews of the market areas where we conducted case studies. Because we hypothesized that MCO decision making might vary with the maturity of the managed care market and the level of competition, we selected market areas with varying managed care penetration rates. A description of the characteristics of plans that were interviewed follows. In order to capture the range of MCO behaviors, we attempted to meet with plans that varied in terms of characteristics such as size, age, model type, national affiliation, and profit status. Because interviewees were promised anonymity, we do not attribute any of our case study findings to individual plans.

3.1.2 Selection Criteria

Our study of managed care decision-making with respect to technology coverage and diffusion was based on case study interviews with managed care organizations, hospitals, and large physician groups in market areas across the country; the national headquarters of five managed care plans; two external review organizations; a technology assessment organization; and a PBM. Appendix 1 lists interview sites. Interviews were conducted from January 1999 through February 2000. While most interviews were conducted in-person, supplementary telephone interviews were also conducted.

Site visits were organized around six market areas. This market-centered approach to selecting MCO sites had two advantages. First, it was cost-effective, minimizing travel expenses and maximizing the number of MCOs visited. More importantly, it enabled us to explore the impact of market structure on MCO decision-making. One hypothesis is that MCOs operating in market areas with higher managed care penetration rates face greater price competition because they compete with other managed care plans, rather than primarily with FFS insurers. As a result, they are more likely to limit adoption of cost-increasing technologies. Alternatively, plans in competitive markets might offer generous benefit packages and larger provider networks in order to attract enrollees. We compare the responses of MCOs in market areas with varying levels of managed care penetration in order to evaluate these hypotheses. In addition, we visited affiliates of several national plans in more than one market area in order to observe how policies vary with market conditions. We also contrast the responses of MCOs within the same market area to assess the extent to which decisions are homogeneous within markets.

Selection of Market Areas The primary criterion for selecting the market areas for managed care organization site visits was the managed care penetration rate. Other criteria considered in site visit selection included: the region of the country; the state regulatory environment; the Medicare managed care penetration rate and concentration; the Medicare

Adjusted Average Per Capita Cost (AAPCC); and the generosity of benefits offered by Medicare managed care organizations in the area.

Managed care penetration was defined at the MSA level because this was the most convenient geographic area for which managed care penetration data were readily available. We used penetration rates reported by Medical Data International (MDI), which calculated managed care penetration rates for 65 MSAs based on enrollment figures obtained from MCOs that serve these markets. Initially, we selected case study sites that represented high, moderate, and low penetration market areas. We defined high penetration as greater than 30 percent managed care penetration, moderate as 20 to 30 percent, and low as less than 20 percent. (Areas with less than 5 percent penetration were not considered candidates.) The cut-offs for these ranges were selected after looking at the distribution of penetration levels across markets. These ranges are somewhat higher than those that have been used in other studies because MSAs tend to have higher managed care penetration rates than other parts of the country.

At the start of the project, it was anticipated that we would conduct site visits in Los Angeles, Boston, Phoenix, Miami, Chicago, Houston, and Birmingham (four high penetration markets, two moderate, and one low). However, site visits to Phoenix, Miami, and Birmingham did not materialize, and site visits to Portland and Seattle were substituted. (Reasons why the visits to these sites did not occur are discussed below) The sites varied geographically with two in the Pacific Northwest, one on the West Coast, another on the east, one in the southwest and one in the Midwest. The one section of the country we did not visit was the southeast, although we did attempt to schedule site visits in Miami and Birmingham. To compensate for not visiting seven market areas, we increased the number of interviews with national headquarters of managed care plans and added interviews with external review organizations. When the site visit to Birmingham did not materialize, we did not replace it with another low penetration market. We were concerned that low penetration markets would have very few managed care plans in the area. Based on our experiences in scheduling site visits through that point in the study, we expected that a large number of plans would refuse to participate. With few plans to choose from, it would be difficult to get a sufficient number of participants to warrant a site visit. In addition, it was likely that the plans were either immature local plans or affiliates of national plans, which either had already been interviewed or had refused to participate in the study at a national level. In light of the information gathered through this point in the study, we expected that a visit to a low penetration market would be relatively uninformative.

For high penetration markets, we visited Los Angeles, Boston, Seattle and Portland. We considered it important to include a market area from California given the degree of competition and the maturity of the market. During our visit to California, which included northern California, we were also able to conduct interviews at the national headquarters of two plans. Boston was selected because of the marked contrast between the importance of managed care in the overall insurance market and in the Medicare market. While the managed care enrollment rate in the overall population is among the highest in the country (56 percent), Medicare managed care enrollment is approximately the national average (15 percent as of March 1998). Despite high overall managed care penetration, the market is relatively concentrated with only four plans in operation. In addition, all of the plans in Boston are locally-based, non-profit entities. Boston provided a particularly interesting case study of the impact of managed care on technology adoption because of the importance of academic medical centers in the hospital market.

Seattle and Portland were chosen as additional high penetration markets. Portland has a relatively mature market; in contrast, despite its high penetration rate, Seattle's market is relatively immature, outside of one well-established plan. In addition, both areas had a large number of managed care organizations from which to choose. Furthermore, these markets could be combined in a single trip because of their close proximity. This further increased the pool of plans that could be contacted for interviews, which was important given the difficulty in scheduling interviews and the number of refusals by plans to participate that we had encountered in other markets (see discussion below).

For moderate penetration markets, we conducted site visits in Chicago and Houston. Chicago was selected because both its Medicare and overall managed care penetration rates were reflective of the average across the country. Chicago also offered the opportunity to conduct interviews at an external technology assessment organization. In contrast, Houston provided an example of a market with high Medicare managed care enrollment, but relatively low concentration, suggesting a high level of competition. Like Boston, academic medical centers have a major presence in Houston's hospital market.

Selection of Managed Care Organizations. Within market areas, we selected an initial group of MCOs to approach for our study based on a range of characteristics. These included model type, profit status, age, national affiliation, and market s share. In general, we limited our interviews to plans that participated in Medicare + Choice because of our special focus on the impact of Medicare policies on technology adoption. In one market we interviewed a plan that was expecting to introduce a Medicare risk product shortly after our visit. We attempted to interview the dominant Medicare plans in the market. Remaining plans were selected to provide variation in characteristics. We also took into account plans that had already been interviewed in other markets (i.e., we did not want to visit local affiliates of a national plan in more than two markets). As discussed below, in many cases we were constrained by the number of refusals received and we simply interviewed any plan in the market area that agreed to participate. Given the high refusal rate, it is possible that our interview sites are not representative of all managed care plans. For example, plans with highly restrictive coverage policies or poorly developed decision making processes may have been less likely to participate.

We defined managed care plans as capitated entities that integrate insurance and service delivery functions. Because of our focus on risk-based managed care, we did not include PPOs in our definition. However, many of the organizations interviewed also offered non-managed care products, including traditional indemnity and PPO plans. The definition of what constitutes a managed care plan has become increasingly blurred over time. Traditional staff and group model HMOs have increasingly given way to more loosely organized network and IPA model plans, and managed care plans may incorporate indemnity-like features such as point-of-service options. Also, fee-for-service insurers incorporate many of the same utilization management mechanisms used by managed care plans, such as prior authorization notification, review of hospital length of stay, etc. It is rare to find a completely unmanaged indemnity product on the market today.[1]

From the beginning, planning the site visits with managed care organizations proved difficult. It took more time than anticipated to make contact with the correct people at the plans. It sometimes required several months of concerted follow-up calls to obtain a response. In other cases, despite our best efforts, plans never replied to requests for interviews. Some plans indicated that our study was a low priority. Because it was voluntary, they simply chose not to participate – they were either too busy or not interested. Indeed, our site visit to Birmingham was canceled because there were only a small number of Medicare+Choice plans in the area and only one agreed to participate. Despite the large number of Medicare plans in Miami, only one of the plans contacted agreed to participate. Although Phoenix was one of our initial sites, we did not attempt to schedule a site visit there because of the hostile environment surrounding HCFA's competitive pricing initiative in that area. Two major national plans decided not to participate in the study at all; in other cases, local affiliates declined to participate and referred us to their national headquarters because coverage decisions were not made locally. This made scheduling site visits problematic in some markets that were dominated by national plans. As a result, our interviews in some areas do not always include the major plans in the Medicare + Choice or commercial market. It also was sometimes difficult to accommodate interviews within the time frame of our site visit. Although we attempted to schedule telephone interviews in these cases, we were not always successful.

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[1] However, a remaining fundamental difference is that providers may bear insurance risk in MCOs, but not in PPOs or traditional indemnity products.

Hospitals and Physician Groups. In addition to interviewing managed care organizations, we also conducted interviews at community hospitals and academic medical centers during the site visits. Because the hospital is the locus for many important technologies, a large number of technology adoption decisions occur at the hospital level and are not under the direct control of MCOs. Many of these technologies are not within the purview of MCO coverage decisions, but nonetheless have important implications for health care spending. Academic medical centers (AMCs) are particularly interesting given that their mission is to advance medical technology because of their role as main research institutions; however, their contracting arrangements with MCOs may impose financial constraints on them that force them to control costs. During site visits, we visited at least one hospital in each market area, with the exception of Portland. We visited an AMC in each area, and in three markets, we interviewed community-based hospitals as well.

We also interviewed large physician groups that had risk-bearing contracts with MCOs in three high penetration areas: Los Angeles, Seattle and Boston. We only interviewed physician groups in high penetration markets because we expected to find contracts that transferred a significant degree of risk to the groups mainly in these areas. Because these groups had contracts in which they received global capitation or percent of premium payments, they were at risk for virtually all services provided. As a result, decisions about covering new medical technologies have been increasingly delegated to them.

National Headquarters of Managed Care Plans. We conducted interviews with the national headquarters of five plans. As we learned during the course of our interviews, many national plans assess new technologies at their headquarters and their policies are implemented regionally. It was, therefore, important to interview the national headquarters to learn about their processes for evaluating and adopting new technologies. Through interviews with national headquarters, we were also able to learn about the interaction between headquarters and regional affiliates for both technology assessment and benefit design.

Other Organizations. In addition to interviewing managed care plans, hospitals, physician groups and the national headquarters of plans, we conducted interviews with other sources. These included external review organizations, both for commercial plans and Medicare; a technology assessment organization, to which managed care plans and others subscribe; and a pharmacy benefits manager.

External review organizations, which provide independent third-party review of appeals of coverage denials by managed care plans, are gaining in importance. External review is mandated in a number of states. Medicare mandates automatic external review of all appealed coverage denials by Medicare+Choice plans, if the denial is not overturned by the plan internal review process. In addition, managed care plans are increasingly implementing external review voluntarily. Because of their importance, we conducted interviews with two external review organizations. Both provide external reviews of coverage denials in commercial plans, whether through state-mandated programs and voluntary plan efforts. One also contracts with HCFA to review appeals of coverage denials by Medicare + Choice plans.

We also conducted an interview with a technology assessment organization. During the course of our site visits, we learned that many managed care plans and hospitals subscribe to outside assessment companies, which provide reviews of new technologies that contribute to the plans' internal coverage decision making. In some instances, subscribers can request reviews of specific technologies that have not already been conducted. Because there are only a handful of organizations that provide this service, many of the plans and hospitals use the same ones.

We also conducted an interview with a PBM. PBMs may be independent firms or off-shoots of managed care organizations and pharmaceutical manufacturers. PBMs contract with managed care plans and self-insured employer groups. Among the services provided by PBMs are: formulary development and management; drug utilization review; mail order pharmacy programs; and disease management programs. As part of the formulary development process, PBMs may conduct assessments of new drugs.

3.1.3 Interview Topics

Our interviews with managed care organizations covered their decision making process in two main areas: technology coverage and benefit design. Hospital interviews addressed the factors influencing their decisions to adopt new technologies, while those with physician groups focused on their coverage decisions. The protocol that was used when conducting interviews with managed care organizations, hospitals, and physician groups is included in Appendix 2.

We asked each organization that we interviewed about their technology assessment process—first, whether they had one and, second, how it was organized. Other questions included the process they used for assessing technologies, how they decide whether to adopt them, and how they control utilization of technologies that have been adopted. We also asked plans, hospitals and physician groups about market characteristics, how important they thought managed care was, and what they thought of its future in the area. Plans were asked also about how they determined their Medicare and commercial benefit packages, how the offerings differed, and how they thought they might change in the future. Hospitals and physician groups were also asked about their relationships and interactions with managed care organizations.

We planned to focus our discussions of the coverage decision making process on specific tracer technologies. Tracer technologies for devices and procedures included: PET scans, lung volume reduction surgery, bone marrow transplantation for solid tumor breast cancer, proton beam therapy, and thin prep Pap tests. Tracer pharmaceuticals included:

Claritan, Viagra, Cox 2 inhibitors, Ceredase, and ABC drugs for multiple sclerosis. Technologies were selected to highlight a range of issues in technology coverage decision making, (e.g., life-saving vs. life-style, high unit costs vs. high volume, unique vs. substitutable). In practice, however, we found that the decision making process was generally invariant to the particular technology being considered.

3.1.4 Overview of Markets Visited

This section provides a brief overview of the six market areas included in our study. Although each area has its unique characteristics, there were some similarities based on the level of managed care penetration. For example, in the high penetration market areas, the interviewees believed that the market was essentially saturated and there was limited opportunity for substantial growth in market share. Plans offered very similar products and competed with each other at the margins (for example, by offering health club memberships). On the Medicare side, plans mostly competed for the people who just recently turned 65. The story was different in the moderately penetrated managed care markets. The managed care market in Chicago was growing slowly and interviewees were uncertain as to whether it would become more penetrated given the organization and character of the city. Houston, on the other hand, was experiencing growth in the market and saw growth in the future as well.

All market areas reflected the strong economic conditions at the time of our interviews. Because of tight labor markets, employers used benefits to attract employees and were willing to pay higher prices for health insurance. Employees favored plans that offered them greater choice, such as PPOs and point of service (POS) options. Thus, we observed a strong push away from more tightly forms of managed care.

Los Angeles. According to MDI, the Los Angeles MSA has a managed care penetration rate of 43 percent.[2] The Medicare managed care penetration rate in Los Angeles County is 41 percent.[3] The area is a mature managed care market with a number of major national plans, as well as well-known tertiary care facilities, and a strong presence of physician groups. The state itself has strong consumer protection laws and recently mandated third party review of coverage denials for patients who are expected to live less than two years. In addition, the state mandates coverage of certain services. In the current climate, plans are reluctant to deny services or treatments to members as two plans have recently received bad publicity regarding denials. One plan in California also was subject to a record-setting judgment for denying a treatment to a member with a terminal illness. In Los Angeles, physician groups and hospitals are consolidating to increase bargaining power and facilitate the management of care within single organizations. The market also appears to be moving away from restrictions on provider choice with the growing popularity of POS products. The general market movement is away from tightly controlled, closed panel HMO approaches.

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[2] Medical Data International, "1998-1999 Managed Care Profile Map" available from http://www.medicaldata.com/MCMap/default.asp; Internet; accessed 28 Feb 2000. Penetration rates are calculated based on enrollment data reported by HMOs for year-end 1997.

[3] Health Care Financing Administration, "Medicare Managed Care Market Penetration for All Medicare Plan Contractors – Quarterly State/County Data Files;" available from http://www.Hcfa.gov/medicare/mpsct1.htm; Internet. Data are reported as of March 1998.

Boston. Like Los Angeles, the Boston MSA is a competitive, highly-penetrated market with 56 percent of the population enrolled in managed care.[4] The Medicare managed care penetration rate in Suffolk County (which contains Boston) is considerably lower, at only 15 percent.[5] The area has traditionally been dominated by four regional, not-for-profit plans. It is renowned for its hospitals and academic medical centers exert a powerful presence. Recent years have seen consolidation among hospitals with the emergence of two major networks. Market competition had kept premium increases low for a number of years. During our interviews, a number of plans noted that their revenues had not kept up with rising costs and indicated that they planned substantial premium increases. Indeed, the largest managed care plan in Massachusetts was placed in state receivership in January 2000 as a result of massive operating losses. Although Boston is a mature managed care market, some interviewees noted that provider behavior has not changed fundamentally; however, hospitals and plans recognized the need for stronger cost-containment measures as health care costs continue to rise.

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[4] Medical Data International, "1998-1999 Managed Care Profile Map" available from http://www.medicaldata.com/MCMap/default.asp; Internet; accessed 28 Feb 2000. Penetration rates are calculated based on enrollment data reported by HMOs for year-end 1997.

[5] Health Care Financing Administration, "Medicare Managed Care Market Penetration for All Medicare Plan Contractors – Quarterly State/County Data Files;" available from http://www.Hcfa.gov/medicare/mpsct1.htm; Internet. Data are reported as of March 1998.

Portland. Oregon is heavily committed to managed care, with a statewide penetration rate of 42 percent.[6] Enrollment in managed care plans is somewhat higher in the Portland area—48 percent.[7] Oregon's Medicaid program mandates enrollment in managed care plans for nearly all eligibles. The Medicare managed care penetration rate is among the highest in the country, with 55 percent enrolled in a managed care plan.[8] Premium rates and drug costs are increasing throughout the market and it was reported that almost every MCO is operating at a loss.

Seattle. Seattle has a high managed care penetration rate at 38 percent.[9] Medicare managed care penetration is 32 percent.[10] However, with the exception of Group Health Cooperative of Puget Sound, a well-established group model plan, managed care plans in Seattle are immature and the market is dominated by PPOs. This is explained by the labor market in Seattle, which centers on Boeing and the software industry. Boeing is strongly unionized and unions have resisted traditional forms of managed care, which they view as a reduction in benefits. The software industry is flourishing and the labor market is tight. Employers offer rich benefits, including higher cost health insurance plans that offer choice, in order to attract and retain employees. In addition, many believe that the "fat" is already out of the health care system in Seattle and managed care cannot make more inroads to lower costs. On the hospital side, Seattle can be described as a niche market, with limited competition between hospitals. According to one of our interviewees, a single hospital accounts for nearly half of the admissions in Seattle.

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[6] Medical Data International, "1998-1999 Managed Care Profile Map" available from http://www.medicaldata.com/MCMap/default.asp; Internet; accessed 28 Feb 2000. Penetration rates are calculated based on enrollment data reported by HMOs for year-end 1997.

[7] *Ibid.*

[8] Health Care Financing Administration, "Medicare Managed Care Market Penetration for All Medicare Plan Contractors – Quarterly State/County Data Files;" available from http://www.Hcfa.gov/medicare/mpsct1.htm; Internet. Data are reported as of March 1998.

[9] Medical Data International, "1998-1999 Managed Care Profile Map" available from http://www.medicaldata.com/MCMap/default.asp; Internet; accessed 28 Feb 2000. Penetration rates are calculated based on enrollment data reported by HMOs for year-end 1997.

[10] Health Care Financing Administration, "Medicare Managed Care Market Penetration for All Medicare Plan Contractors – Quarterly State/County Data Files;" available from http://www.Hcfa.gov/medicare/mpsct1.htm; Internet. Data are reported as of March 1998.

Chicago. Cook County, with Chicago as the county seat, has a moderate managed care penetration rate. Of the total population, approximately 27 percent is enrolled in managed care.[11] According to respondents, the Medicare managed care market, which stands at 16 percent,[12] is growing slowly in the area. Medicare managed care plans in Chicago mainly compete with fee-for-service and Medigap plans, not other managed care plans. The Medigap market is large and profitable in Chicago for Blue Cross/Blue Shield, which is the main insurer. As the home of both the American Medical Association and the American Hospital Association, plans attribute slow growth and moderate penetration to a strong anti-managed care sentiment among providers. There are other reasons why MCOs are not gaining ground in Chicago. As in other areas, the economy is strong and the labor market tight. There are also no dominant employers or employer purchasing coalitions—employers negotiate individually with plans. Also, Chicago is organized around neighborhoods. Each neighborhood has its own local hospital and physicians, which residents prefer to patronize. They resist being funneled into managed care referral networks. Although potentially large and competitive, the city and its medical market (with the exception of tertiary care) is balkanized into different neighborhoods.

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[11] Medical Data International, "1998-1999 Managed Care Profile Map" available from http://www.medicaldata.com/MCMap/default. asp; Internet; accessed 28 Feb 2000. Penetration rates are calculated based on enrollment data reported by HMOs for year-end 1997.

[12] Health Care Financing Administration, "Medicare Managed Care Market Penetration for All Medicare Plan Contractors – Quarterly State/County Data Files;" available from http://www.Hcfa.gov/medicare/mpsct1.htm; Internet. Data are reported as of March 1998.

Houston. Although managed care had a slow beginning in Houston, its market share has been increasing rapidly in recent years. Approximately 30 percent of the population is enrolled in managed care.[13] Enrollment in managed care is also growing rapidly among the Medicare population, with 24 percent of beneficiaries in Harris County enrolled in a Medicare + Choice plan.[14] Despite the relative growth in managed care, physicians in the Houston area have been slow to organize themselves and enter into capitated arrangements. The physician practice management market has undergone several changes, with some groups merging, others dissolving, and one declaring bankruptcy. Because of this instability and the limited number of physician groups, some of the MCOs have had to scale back their risk arrangements with physicians. On the hospital side, Houston is dominated by the Texas Medical Center, a 675-acre complex of nationally renowned hospitals and clinics. Texas was also the first state in the nation to allow managed care plan enrollees to sue their health plans for malpractice and the state mandates external review of denials.

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[13] Medical Data International, "1998-1999 Managed Care Profile Map" available from http://www.medicaldata.com/MCMap/default. asp; Internet; accessed 28 Feb 2000. Penetration rates are calculated based on enrollment data reported by HMOs for year-end 1997.

[14] Health Care Financing Administration, "Medicare Managed Care Market Penetration for All Medicare Plan Contractors – Quarterly State/County Data Files;" available from http://www.Hcfa.gov/medicare/mpsct1.htm; Internet. Data are reported as of March 1998.

3.1.5 Overview of Plans Interviewed

In total, we interviewed eighteen managed care plans in six market areas and the headquarters of five national plans. The managed care organizations that we visited varied in characteristics. One of the smaller plans had approximately 600 Medicare enrollees, while one of the larger plans had over 500,000. The majority of plans had at least 10,000 Medicare enrollees. The number of commercial enrollees ranged from 10,000 to over 2 million, with most of the plans having more than 100,000 members.

The plans we interviewed were fairly evenly split between for-profit and not-for-profit status, although all the plans we visited in Portland and Boston were not-for-profit. More than half the plans we visited across the country were part of national managed care organizations. California was home to two of the oldest plans – one entered the market in 1929 and the other in 1943. We also visited with new managed care plans in Houston and Seattle, both of which began in 1997. In most markets, group and IPA models were the most prevalent models while staff and network models were less common.

3.2 Device and Pharmaceutical Manufacturers

3.2.1 Selection Criteria

HER selected manufacturers based on a prior selection of tracer technologies. (It should be noted that these are not the same tracer technologies used in our interviews with MCOs.). We first chose a particular product line, then identified one or more manufacturers producing the technology. Once a firm was selected, a battery of questions covered not only the product line in question but the overall set of products and investment decisions of the firm.

The following criteria, derived in part from the literature, were considered in identifying the device and drug tracer technologies:

- Visibility to Patients;
- Cost-saving vs. Cost-increasing;
- Current Diffusion Level;
- Inpatient vs. Outpatient Locus; and
- Medicare Orientation.

Visibility of the technology to patients is of major importance in its adoption by providers and managed care entities. A literature exists on how technologies are used by hospitals to compete with each other for patients. We surveyed manufacturers of both visible and "invisible" technologies. Our goal was to test, subjectively, for differences in market demand and MCO decision making between visible technologies that are potential quality signals providers can use to attract patients and those that may be valuable in patient diagnosis and/or treatment, but remain unknown to patients.

We focused on technologies perceived as cost-increasing by payers, as well as those perceived as cost-decreasing. Managed care is expected to discourage adoption of cost-increasing technologies and encourage adoption of those that are cost-decreasing.

All technologies follow an S-shaped diffusion curve of some sort, with initial slow adoption followed by rapid adoption, then market saturation. We clearly did not want to limit the case studies to technologies just in their take-off stage. Rather, we sought a mix of technologies that covered a range of diffusion levels.

Given the major shift to ambulatory care, we sought a balance of inpatient versus outpatient-oriented technologies. Historically, the vast majority of expensive new technologies have been adopted in a hospital inpatient setting. Yet, more and more, technologies are being designed either to reduce inpatient admissions or to function independent of inpatient support. Medicare's PPS per case payment system and managed care plans provide different signals regarding inpatient utilization. Managed care cost containment is predicated on keeping patients out of expensive acute hospitals. Medicare per case payment encourages hospitals to adopt both patient-admitting technologies and those that shorten stays once admitted.

Finally, the government has a special interest in the short- and long-run impact of Medicare managed care on technical innovation and diffusion. Presumably, Medicare would have no impact on neonatal technologies but should have a major impact on chemotherapy, arthritis, and major joint replacement innovations. Thus, we emphasized firms producing technologies used by the elderly, expecting that they would be more knowledgeable about Medicare managed care trends and would give more meaningful answers to questions relating to Medicare MCO growth.

3.2.2 Types of Technologies and Manufacturers

HER staff in consultation with HCFA and the Technical Advisory Group, selected key tracer technologies across a range of clinical areas experiencing rapid technological innovation. They include a range of technologies reflecting each of the selection criteria of visibility, costliness, diffusion level, delivery locus, and Medicare orientation. We then selected manufacturers of these technologies. More than one manufacturer will generally produce a particular device or drug. Moreover, some large manufacturers, will make a wide range of related products. In addition to products, selection of firms took into account geographic proximity so that site visits could be organized around more than one firm.

As was the case for our MCO case studies, obtaining the cooperation of manufacturers was a difficult and time consuming process. In the end, a number of the firms that were selected for the study either never responded to repeated contacts or refused to participate. As a result, our R&D case study sites also may not be representative of the overall device and pharmaceutical industries.

In the end, extensive interviews were conducted with four device companies, three of them on-site and a fourth by telephone.

1. Boston Scientific in Natick, Massachusetts. This company makes aortic balloons and surgical endoscopes for angioplasty and vascular surgery.
2. Hewlett-Packard in Andover, Massachusetts. This company makes a range of computer-related products such as ultrasonic scanners, patient and fetal monitors, and ECG machines.
3. GE Medical Systems in Waukesha, Wisconsin. This company is best known for its radiographic line of products including CT and MRI imagers and echocardiographs.

4. Medtronic in Minneapolis, Minnesota. This company makes heart valves, aortic balloons and stents, and different types of implantables.

Interviews were conducted with three pharmaceutical manufacturers, one in person and two by telephone.

1. Genzyme Genetics in Framingham, Massachusetts. This is a large biotechnology company with several product lines involving neonatal screening, tissue repair, adult screening tests, DNA testing and genetic treatment of rare neurological diseases.
2. Smith-Kline Beecham Pharmaceuticals in Philadelphia, Pennsylvania. This is a large established pharmaceutical company manufacturing ulcer drugs (Tagamet), antipsychotics, as well drugs for nausea control and attention disorders.
3. Pfizer, Inc. in New York and Connecticut. This is a large, established pharmaceutical company manufacturing antianginal calcium channel blockers, antibiotics, antidepressants, and the new erectile dysfunction drug Viagra.

The final set of firms interviewed produced a broad range of technologies, which taken as a group encompass the range of criteria used to select tracer technologies. All of the manufacturers interviewed had products that would be used by the Medicare population. For example, several of the firms had an emphasis on cardiovascular technologies (Boston Scientific, Medtronic, and Pfizer). The technologies produced by our case study sites also varied in their visibility to patients. ECGs (Hewlett-Packard) and stents (Medtronic) tend to be invisible. Pfizer's Viagra is certainly a highly visible technology that is viewed as cost-increasing by payers. Endoscopic surgery (Boston Scientific) is often considered cost-reducing, while heart valves (Medtronic) and MRIs (GE) add to diagnosis or treatment costs. Stents and implantables (Medtronic) are rapidly diffusing, whereas CT and MRI imagers (GE) and ulcer drugs (Smith-Kline Beecham) are well-diffused. Psychotherapeutics (Pfizer, Smith-Kline Beecham) and scanners (Hewlett-Packard) have an outpatient orientation. Heart valves and aortic balloons (Medtronic) are used on inpatients, as are patient monitors (Hewlett-Packard). Finally, we included a biotechnology company (Genzyme Genetics) because of biotechnology's key role at the cutting edge of medical innovation.

A brief interview was conducted with staff at Summit Technology in Boston, a very small company exclusively providing a new form of laser eye surgery. This initially appeared to be a promising subject as a highly visible outpatient technology that signals complex high quality care. However, it is not covered by any form of insurance currently. As a result, they were not included in the findings.

Interviews were conducted with several individuals in the firms. Depending on the firm, interviewees included individuals in the marketing department, R&D managers, reimbursement analysts, and cost effectiveness analysts.

In addition to the core firm interviews, some related interviews were conducted. Medical Alley Associates in Minneapolis is a non-partisan organization funded to develop cost effectiveness methods related to devices. Analytic services are provided to hospital trustees on devices, as well as to HCFA on coverage decisions. While helpful, the organization was not in a position to answer the questions in our protocol. A brief interview was also conducted with Candy Littell of the Health Industry Manufacturers Association (HIMA).

3.2.3 Interview Topics

Our interviews with device and pharmaceutical manufacturers examined the impact of the spread of managed care, and particularly Medicare managed care, on their R&D agendas. The interview protocol is included in Appendix 2. Among the issues discussed were how plans seek to influence MCO coverage decisions, the effect of market competition, and the impact of managed care on the development of new product lines. We also asked manufacturers about the importance of managed care for their products, both currently and projected for the future. In addition, our interviews sought to put the effects of managed care into context by learning about other factors that drive R&D decision making. Among these are the role played by scientific advances outside of the health care sector and population demographics. We also asked manufacturers about payment policies generally, particularly Medicare policies.

4

Case Studies of Technology Coverage Decision Making in Managed Care Organizations

4.1 Introduction

Managed care plans have a variety of tools at their disposal to control service use and costs. In addition to negotiating discounted rates or using bundled payments that off-load risk to providers, MCOs have adopted a range of strategies to manage utilization of services. Perhaps the most visible and controversial technique is placing limitations on the use of certain services by establishing criteria for when, if at all, a service will be reimbursed. These criteria are sometimes enforced using mechanisms such as prior authorization, utilization review, and drug formularies. Managed care plans have come under increasing fire for imposing these restrictions. Critics contend that treatment guidelines established by MCOs pose access barriers that interfere with physician decision making and place financial concerns over the best interests of patients. Recent discussions of Patients' Bill of Rights and other consumer protection legislation at the federal and state levels have been fueled by a growing distrust of the managed care industry. Managed care plans, on the other hand, argue that treatment coverage guidelines only restrict access to unnecessary or inappropriate services. Not only do such guidelines promote the most efficient use of our health care dollar, they also improve quality of care and may even protect patients from potentially harmful treatments. While coverage decision making is not unique to managed care plans, there is a widespread perception that they adopt more restrictive policies than other insurers and enforce them more stringently.

This chapter describes our findings with respect to technology coverage decision making. Questions addressed in our discussion of technology decision making include:

- Who makes coverage decisions?
- When are coverage decisions made?
- What are the procedures used to make coverage decisions?
- What role do external influences play in coverage decisions?
- To what extent do coverage decisions vary by plan or market area?
- How is the utilization of covered technology controlled?
- How do MCOs influence decision making by hospitals and physician groups?

The following chapter discusses benefit design decisions. In order to understand the distinction between benefit design and technology coverage decisions and how they interrelate, it is important first to clarify the use of the term "coverage." From the perspective of managed care plans (indeed all insurers), coverage policies are statements found in benefit design documents about broad categories of service that they are contractually required to provide to an insured population. While the language varies, benefit design documents typically contain statements limiting coverage to services that are medically necessary, effective, and appropriate to the condition being treated. In addition, benefit design documents often explicitly exclude coverage of certain categories of service.

For example, virtually all contracts exclude coverage of treatments that are considered investigational and experimental. Other common exclusions include cosmetic procedures, treatment of specific conditions (e.g., obesity, infertility, sexual dysfunction), and, depending on the benefit package selected, entire categories of service (e.g., drugs, vision services, physical therapy, etc.).

While the investigational/experimental exclusion is clearly of considerable relevance to new technologies, medical necessity and effectiveness criteria also are often used to limit their coverage. When a plan sets a policy about covering a *particular* treatment, they are making a determination about whether and, often, under what circumstances a treatment meets the coverage criteria stated in the benefits design statement. Determinations as to whether a treatment is experimental or under which clinical circumstances it constitutes medically necessary and appropriate care are set out in medical policy guidelines for specific services. However, the benefit design document defines the plan's contractual obligation and provides a legal basis for denying coverage of certain services.

Although most benefit design documents specify that only medically necessary services are covered and that investigational/experimental procedures are excluded, plans have considerable latitude in their definition of these terms and in their judgments about how they apply to specific treatments and individual cases. As a result, there is potentially substantial variation across plans in the coverage decision for a given case. In an effort to reduce some of this variability, recent legislative initiatives (for example, the Daschle-

Kennedy Patients' Bill of Rights Bill proposed in 1999) have sought to codify the definition of medical necessity.

In the following discussion, we use the term "technology coverage decision" to refer to medical policy guidelines for coverage of specific services. This section discusses findings from our case study interviews about the processes used by managed care plans to make technology coverage decisions, the factors influencing these decisions, and implications for the ability of MCOs to limit the adoption and diffusion of new technologies.

Our consideration of new technologies includes procedures, devices, and drugs. However, MCOs rarely make coverage decisions about devices because they reimburse for them directly only in limited cases (for example, durable medical equipment). Typically, plans make coverage decisions about diagnostic and therapeutic procedures, which in turn may involve devices. Of course, coverage decisions about these procedures have important implications for the market for a new device. Similarly, many devices used in the inpatient setting are simply incorporated into a bundled case rate or per diem payment to the hospital. Again, these payment incentives may influence the likelihood that a hospital will purchase a new device, but hospitals are not directly reimbursed for devices.

4.2 Who Makes Technology Coverage Decisions?

Nearly all plans interviewed had one or more formal committees responsible for making technology coverage decisions. Typically, one committee is charged with setting policy for medical therapies, surgical procedures, diagnostic procedures, and devices. These committees operate under varying names, most often a variant on technology assessment (TA) committee or medical policy committee. In some plans, there are distinct committees responsible for conducting technology assessments and for setting medical policies. In these cases, the TA committee analyzes published literature and other evidence on a new technology. This analysis provides input to the medical policy committee, which sets the guidelines. In general, a separate pharmacy and therapeutics (P&T) committee is charged with making drug coverage decisions and setting the plan formulary.[1] Smaller, younger plans do not always have formal committees. Instead, coverage decisions are made on an ad hoc basis by "a committee of one"—the plan medical director—and the plan formulary is set using a pharmacy benefits manager (PBM).

The specific composition of the committees varies from plan to plan, but in all cases there is a strong clinical orientation and physicians are predominant. These physicians are usually part of the plan administration, but a few plans include members of their provider panel. P&T committees also include pharmacists. If there is a TA committee that is distinct from the medical policy committee, it usually serves more of a research than policy-making function and is not staffed by physicians. Instead these distinct TA committees often use nurses, epidemiologists, and other non-clinical analysts.

The clinical orientation of medical policy committees reflects a philosophy that coverage recommendations should be grounded in scientific evidence. Some plans' committees have an exclusively clinical perspective. In these cases, implementation of guidelines, including consideration of their financial and legal implications, is left to separate committees. Other plans do not maintain as strict a division and incorporate staff from other areas of the plan (such as the legal, finance, or benefits departments) based on the philosophy that these departments need to communicate during the decision making process. In a few cases, the TA/medical policy committees include external members such as a bioethicist or community representatives. In addition, committees may call on outside experts in a specific clinical area or medical society representatives. However, these external representatives are involved on an ad hoc basis and do not have voting rights.

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[1] Injectable drugs usually are not within the purview of the P&T committee.

Acknowledging public perceptions that medical policy guidelines may act as barriers to care and intrusions into the doctor-patient relationship, some plans have taken steps to dispel distrust of their decision making process. One plan opens its committee meetings to the public. Another broadly disseminates its medical policy guidelines and makes them available to the general public through a variety of media, including the plan's website.

For national plans that operate in multiple markets, technology coverage decision making is centralized and conducted out of the plan headquarters. However, the TA/medical policy committee usually incorporates regional plan representatives. Coverage policies are uniform across market areas, although they are modified when necessary to conform to state mandates. While some national plans have always had centralized coverage decision making, others have only adopted this in recent years. Several factors have contributed to this greater centralization of technology coverage decision making. First, as the systematization and analytic rigor of the coverage decision making process has grown, so have the associated costs. Instead of replicating these analyses in local markets, centralization allows plan to capture economies of scale. Second, it promotes the internal consistency of plan policy. If decisions are based on scientific evidence, it is difficult to explain why a technology would be covered in one market, but not another. Finally, consistency is particularly important to employers operating in multiple markets, which comprise a large share of the subscriber base in national plans. These employers need to ensure that their employees in different locations have comparable benefits.

4.3 When are Technology Coverage Decisions Made?

Managed care plans conduct technology assessments and have medical policy guidelines for only a small fraction of the services they cover. Not only is it not feasible to assess every medical technology, in many cases it is unnecessary because there is little controversy about its appropriate use. For example, one plan estimated that, in total, they have approximately 200 medical policy guidelines. A large national plan reported that they assess between 60 and 80 medical technologies a year, while one local plan reviews about a dozen annually. Small, young plans rarely set medical policy guidelines. Instead, coverage decisions tend to be made on a case-by-case basis by the plan medical director.

Plans use a number of criteria to select technologies for review. These include:

- high level of interest among subscribers or providers;
- high potential costs, either because of high unit costs or high expected use rates;
- high level of controversy regarding alternative treatment strategies;

- media exposure;
- potential legal liability;
- reasonable potential for improved outcomes; and
- competitive concerns.

For the most part, plans are reactive in identifying technologies for review. Generally, consideration is prompted by member or provider requests for coverage. National plans usually receive input from their local affiliates. Other sources include the media, provider member recommendations, the Food and Drug Administration (FDA) (for drugs and devices), and technology assessment organizations. Plans usually only conduct a review if they receive multiple requests for coverage and rarely set a policy if they believe a coverage request represents an isolated case. In some instances, they may take a more proactive stance even if they have few or no claims for a service. This typically occurs if there is a high level of media exposure, high potential legal liability, or if demand is expected to grow rapidly once the technology comes on the market. A plan may also feel compelled to review a technology used to treat a life-threatening condition, particularly if there is a physician advocating for its coverage.

P&T committees are more proactive and rely less on claims for identifying review subjects, most likely because the FDA approval process readily identifies all new drugs that are introduced to the market or that will be coming out soon.[2] However, many P&T committees will not consider a new drug for inclusion in their formulary during the first six months it is on the market. This enables them to avoid the initial high levels of use they say often immediately follow the introduction of a new drug and provides an opportunity to observe experience with its use. Several plans noted the advantage of this "wait and see" attitude with respect to the diet drug Fen-Phen. However, in some cases (e.g., Viagra), plans feel there is too much interest in a new drug to defer a decision. Some plans also expected that they would not be able to delay consideration of the new Cox-2 inhibitors.

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[2] In contrast, there is no comparable approval process for new procedures, although devices receive FDA approval.

The National Committee for Quality Assurance (NCQA) requires plans to review their medical policies as part of the accreditation process. However, this is generally a pro forma review. A technology may receive more extensive reconsideration if important new studies are published. For example, one plan reversed its decision to deny coverage of acupuncture for pain management following publication of an NIH consensus panel report. Reconsideration may also be prompted by the introduction of a new therapy that is a potential substitute. However, several plans noted that most new technologies are additive and it is very difficult to deny coverage of something that would have been approved in the past.

4.4 How Are Technology Coverage Decisions Made?

4.4.1 Decision Making Process

NCQA has set the following broad standards that plans are expected to conform with in their coverage decision making process:

- a well-defined process for making decisions about covering medical treatments and services;

- fair and consistent decisions about provision of medical treatments and services; and
- evidence that qualified health plan professionals make decisions about medical treatments and services.[3]

Within these broad parameters, we found that the process for making technology coverage decisions differs substantially between large, established plans and small, young plans.

As noted previously, young plans are less likely to set formal technology coverage policies. Instead, the plan medical director typically makes decisions on an ad hoc basis. If the volume of requests to cover a technology is high enough, the medical director may ask another committee (either a benefits committee or a technology review committee) to set a formal coverage policy. Medical directors of small plans draw on a variety of resources to make their coverage decisions, including published literature, assessments published by TA organizations, HCFA coverage policies, the Internet, and plan physicians. In addition, these medical directors indicated that they engage the treating physician in a dialogue and most indicated that they try to be flexible in their decisions. One noted that he would find it difficult to deny coverage of an unproven technology for a life-threatening condition if there were no other treatment alternatives available.

Established plans, on the other hand, usually have a formal technology assessment process and they are far more likely to have one than they were ten years ago. In part, this is because the state-of-the art in technology assessment has advanced considerably during this time. Plans also feel that a formal decision making process provides greater public accountability and counters distrust of the managed care industry. Some plans also view the more formalized process as a protection against medical liability claims because it enables them to document and justify their decisions.[4]

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[3] National Committee for Quality Assurance, "What NCQA looks for in a Health Plan: Access and Service," available from http://www.ncqa.org/pages/hprc/index.html; Internet: accessed 23 May 2000.

Although the specifics of the coverage decision making process differ from plan to plan, the broad outlines are similar. In the first stage, the literature on a new technology is reviewed and summarized. While some plans limit their consideration to published, peer-reviewed literature, others do not impose as stringent requirements. Plans may also review assessments conducted by government agencies (e.g., AHRQ) and HCFA's coverage policies. In addition, they may consult with medical experts.

While some plans conduct their own literature reviews, virtually all plans rely to some degree on reviews conducted by TA organizations. Example of TA organizations that plans commonly subscribe to are: the Technology Evaluation Center (TEC), which is a collaboration between the BlueCross BlueShield Association and Kaiser Permanente; the Emergency Care Research Institute (ECRI); and HAYES, Inc. While some plans use this information to supplement their own literature reviews and analyses, others rely almost exclusively on the work of these TA organizations. Some plans subscribe to multiple TA vendors, while others have one preferred source of information.

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[4] However, a study analyzing 203 Federal and State court cases from 1960 and 1994 found no significant difference in decisions about whether an insurer should cover the treatment based on whether they used a formal assessment process, local or ad hoc review, or no explicit assessment at all (Anderson, Hall, and Smith, 1998). Instead, the most important determinants were the insurance contract language, severity of the patient's condition, and the ultimate effectiveness of the treatment for the patient.

The TA organizations typically provide a summary of the scientific evidence related to a technology, although they do not make coverage recommendations per se. For example, TEC assesses whether, and for what clinical indications, the technology meets their evaluation criteria (described below). Although the assessments of TA organizations are simply an input to the plan decision making process, they provide a natural basis for medical policy guidelines. While plans can and do adopt policies that diverge from the TA organization's assessment, the plans interviewed report that their policies closely mirror the conclusions of these assessments in the majority of cases.

Based on the information gathered from various sources, the committee evaluates a technology against an established set of criteria. While the exact criteria vary from plan to plan, they generally focus on determining whether the technology is safe and effective. Technologies are also compared to established alternatives, if any. Several plans have criteria that strongly resemble those used by TEC:

- The technology must have final approval from the appropriate government regulatory bodies (drugs, biological products, devices, and diagnostics only).
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- The technology must improve the net health outcome.
- The technology must be as beneficial as any established alternatives.

- The improvement must be attainable outside the investigational settings.[5]

The committee will then develop and vote on a medical policy guideline for the technology. Plans report that there is generally little dissension on the votes. One plan tables consideration of a medical policy guideline until a later meeting if they are not able to achieve consensus.

The medical policies fall in three categories: cover; cover with conditions; do not cover. A blanket no coverage decision is typically issued if the technology is of unproved effectiveness (i.e., it is judged to be investigational/experimental) or unsafe. Although plans have a blanket coverage policy for the vast majority of medical services, this is rarely the case when a technology has gone through the formal coverage decision making process because there is typically some controversy about its appropriate use. Most often, medical policy guidelines set medical necessity criteria that define the specific clinical indications for which a technology is covered. For example, a patient may be required to meet diagnostic criteria or to have failed at other treatment alternatives. According to the director of technology assessment at one plan, "It is difficult to have a blanket policy because there is no such thing as an average patient." Others noted that most technologies have value in at least some circumstances, so that blanket no coverage decisions are unusual.

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[5] "Technology Evaluation Center Criteria," The Technology Evaluation Center, BlueCross BlueShield Association.

4.4.2 Role of Cost in Coverage Decisions

Cost considerations do not play a clear-cut role in the coverage decision making process. Most plans interviewed stated that cost is not a criterion in their coverage decisions and they will not deny coverage of an efficacious technology simply because it is high cost. If there is an alternative existing technology, plans may consider relative cost effectiveness. However, plans typically do not conduct formal cost effectiveness studies.[6] Some interviewees noted that data needed for cost effectiveness studies usually are not available and there are many unknowns (e.g., what are the side effects of a treatment and what is their financial impact). TA organizations also do not consider cost in their technology reviews. Although TEC has conducted a limited number of cost effectiveness analyses (three at the time of our interview), they are too expensive to do regularly.

However, it is not the case that cost plays no role in coverage decisions. Most fundamentally, the very nature of the process takes cost into account. As a respondent at one plan noted, coverage decisions typically are not made for low cost technologies so that only those with high potential costs are subject to this level of scrutiny. In addition, cost factors into the benefit design. If a technology is expected to have a substantial cost impact, a plan may decide to require prior authorization (e.g., for bone marrow transplants) or limit covered quantities (e.g., Viagra). However, a separate group usually makes these decisions. If it finds evidence of a technology's effectiveness based on TEC criteria, one plan creates a balance sheet to analyze its impact on the organization, including its expected use and cost. Nonetheless, they will cover a high cost technology if it is more efficacious than existing ones. The balance sheet provides information on how they may need to allocate resources to accommodate the new technology. For example, this plan projected that covering gastric reduction surgery for morbid obesity would cost the plan $4 million annually. In response, the plan developed more explicit treatment criteria in order to reduce the expected volume. In another instance, based on predictions that Fosamax could cost the plan as much as $20 million a year (nearly 40 percent of the current drug budget), they undertook a comprehensive evaluation of osteoporosis treatment, including treatment guidelines and alternatives to drug therapies.

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[6] Cost effectiveness analysis compares the costs of a treatment, usually measured in dollars, against the health benefits produced, expressed in terms such as the number of cases detected or the number of lives or years of life saved. The goal of cost effectiveness analyses is to maximize health benefits achievable with a given level of resources. Among the many considerations in conducting cost effectiveness analyses is the time horizon over which health costs and benefits are measured and the rate at which those occurring in the future are discounted. For a more detailed discussion of cost effectiveness analysis, see Weinstein and Fineberg (1980).

4.4.3 Drug Coverage Decision Making

The procedures used by P&T committees to make drug coverage decisions are similar in many respects to those used by TA/medical policy committees. The committee reviews the literature on a new drug (including literature provided by the manufacturer), evaluates it against established criteria (safety, efficacy, and performance relative to existing drugs), and makes a decision whether to include it on the plan formulary. In addition, P&T committees develop guidelines for appropriate use of new drugs. Although external TA organizations such as TEC do not review drugs, many plans use a PBM as a resource in their assessments.

However, there are some fundamental differences between drugs and other medical technologies. First, unless a plan has a restrictive formulary and only covers drugs that are explicitly listed, formulary decisions mainly affect beneficiary cost sharing and do not preclude coverage entirely. Second, cost is a more explicit factor in formulary decisions because many drugs are therapeutic substitutes. When substitutes exist, a plan may only include one agent on its formulary. In these cases, price is usually a primary determinant, although plans also consider dosing requirements and other factors that affect patient compliance. These decisions are not without controversy, however. For example, one plan drew fire from mental health advocacy groups after it dropped Prozac from its formulary, although it included several lower-cost selective serotonin re-uptake inhibitors (SSRIs). Advocates contended that there is a great deal of individual variation in the side effects and effectiveness of specific SSRIs.

Rising drug costs were a central concern to most of the plans we interviewed. Many cited double-digit increases in their spending for drugs. One noted that their drug expenditures now exceeded those for hospitals. MCOs are concerned about the large number of new drugs on the horizon, particularly the new biotechnology products. Some also asserted that the FDA Modernization Act has brought new drugs onto the market sooner than they would have in the past, with less evidence available to assess their safety and efficacy.

4.4.4 Appeals Process

All plans have procedures that allow members and providers to appeal denials. In addition, some plans have an exceptions process that allows a provider or patient to petition for a waiver of the coverage policy based on the indications in a specific case. The medical policy guidelines at one plan explicitly provide for "individual consideration" of cases that do not conform with the treatment guidelines. Some of this plan's guidelines include examples of specific circumstances that warrant individual consideration. The medical director felt this explicit exception process was particularly important given the concentration of teaching hospitals in the plan's market area.

4.5 Coverage of Investigational/Experimental Technologies

As noted previously, all plans exclude coverage of technologies that are deemed investigational/experimental. Thus, plans generally only cover FDA-approved devices and drugs. However there is no comparable approval process for procedures and the definition of these terms is fraught with controversy. Decisions are especially sensitive when they involve life-threatening conditions such as cancer. Many plans cited instances when they covered a treatment that they considered investigational/experimental because the negative publicity generated by a coverage denial was too great. However, in these instances the decision is usually couched in a way that attempts to avoid setting a precedent for future cases. Some plans try to shield themselves from some of these controversies by enlisting outside consultants (such as external review organizations) to review transplants and other difficult cases.

Some interviewees questioned the usefulness of the terms investigational and experimental. One noted that most of the technologies they review could be considered experimental in the sense that there is some controversy about standard practice. Another contended that medical efficacy criteria subsume the investigational/experimental designation; i.e., there is not a sufficient body of scientific evidence to establish their efficacy. However, one interviewee at an external review organization noted that it can take several years for studies to appear in peer-reviewed journals. By restricting their technology assessments to published peer-reviewed literature, MCOs may continue to label technologies as investigational/experimental and deny coverage well past the time that experts in the field have recognized them as effective.

Some experts have noted the dilemma that covering investigational/experimental technologies poses. On the one hand, it may never be possible to evaluate the effectiveness of a treatment if it receives widespread coverage before its effects are known. On the other hand, it can be difficult to enroll adequate study populations in clinical trials and generate the scientific evidence needed to establish a new technology's effectiveness, given that plans typically do not cover treatments provided through a clinical trial (NIHCM Foundation, 1999). In response to this Catch-22, some plans have instituted limited coverage of experimental treatments provided through an approved clinical trial (New York Times, December 16, 1999). For example, one of the plans interviewed will cover treatments through a clinical trial in life-threatening situations where there is a likelihood of death within twelve months. As another example, some plans allow non-Medicare enrollees to participate in the lung volume reduction surgery clinical trials.

4.6 Do Technology Coverage Policies Vary Across Products?

Plans generally prefer to have policies that are internally consistent. It is difficult to justify covering a technology in one product, but not another, particularly if they believe they have a well-substantiated, evidence-based coverage determination process. If Medicare policy conflicts with the plan's internally developed guidelines, they will have to make a decision about how to reconcile the two. Medicare+Choice plans are required to cover any service that would be covered under FFS Medicare even if the plan does not cover it for their commercial products. Most MCOs are reluctant to bring their commercial products into conformity with Medicare rules. For example, Medicare requires coverage of transmyocardial revascularization, but many plans consider this procedure experimental and do not cover it in their commercial products. Some plans expressed the opinion that Medicare coverage policy can be highly politicized and not always grounded in good science. However, a few plans used Medicare coverage policy as an input to their own coverage decisions for their commercial products.

On the other hand, a number of plans will cover a technology in their Medicare products that is covered in their commercial products, even if it is not covered under FFS Medicare. Before its decision to cover lung volume reduction surgery performed under a clinical trial, Medicare did not cover this procedure. However, one plan interviewed had already decided to cover the surgery and included it in their Medicare products because they were not comfortable having different coverage policies for different product lines. Other Medicare+Choice plans refuse to cover procedures that are not covered under FFS Medicare, even if they are covered in their commercial products.

Several of the plans included in our case study offer indemnity, as well as managed care, products. Without exception, these plans' medical policy guidelines apply uniformly to their managed care and indemnity products. One medical director noted that they cover efficacious technologies and efficacy does not change with the form of insurance. However, another interviewee observed that it is more difficult to enforce guidelines in the indemnity environment. Nonetheless, adoption of technology coverage policies is not unique to MCOs. In this respect, the difference between FFS and managed care plans is mainly one of degree.

4.7 Do Technology Coverage Policies Vary Across Markets?

We hypothesized that technology coverage decisions would be influenced by market characteristics and that coverage would be more restrictive in areas with a mature managed care market. While we found some support for this hypothesis, there are significant factors that lead to uniformity across market areas.

First, as discussed earlier, national plans centralize their coverage decision making and, outside of any local mandates, policies are consistent across the country. Large national employers, who seek consistency for their employees located in disparate markets, have helped foster the trend toward centralization. However, coverage policies are implemented locally and there may be local variation in the interpretation of medical guidelines with respect to a particular case. Although it is difficult to assess whether there is in fact significant variation, respondents at the national headquarters of the plans we interviewed did not express concern that policies are not interpreted uniformly at the local level. One plan described substantial efforts to educate local medical directors about how to make decisions in order to promote uniformity. Each month a "tough case" is reviewed in a conference call with the local medical directors, including how to get information to make a decision, the criteria for making a decision, and resources at the plan headquarters to assist in making a decision. Local affiliates also did not voice concerns about applying standardized, national policies to their local market conditions and did not feel this placed them at a competitive advantage. The local affiliates stressed the fact that policies are based on scientific evidence and that they have significant input to the policy-making process.

Second, assessments by outside TA organizations form an important basis for the policies of many plans. Because plans draw on the same handful of TA firms, their policies are likely to strongly resemble each other. Most plans could cite instances where their policy diverged from that of the TA organization, but these were the exception rather than the rule. One plan stated that using TEC insulated it from industry and local provider influences. In addition, the plan's decisions are not driven by the opinion of a single representative from a given medical specialty as they often had been in the past. Nonetheless, the plan did not follow TEC recommendations in a few instances where local providers felt it did not reflect standard practice in the area. In another case, the plan decided to cover a procedure, despite insufficient evidence of clinical efficacy, after being lobbied by its developer, a local biotechnology firm. In addition, this plan explicitly provides for exemptions from their coverage policy through an individual consideration process.

Standardization of practice is another important impetus for uniformity. Several interviewees noted that a consensus about the appropriate use of a new technology usually emerges over time within the medical community.[7] Although plan policies may differ when a technology is first introduced, they mainly arrive at the same coverage decisions eventually. For drugs, the specific agents included on plans' formularies may differ because of negotiated discounts, but all plans include a drug from the therapeutic class.

A peculiarity of Medicare policy may create variation across markets that causes particular problems for national plans. Many Medicare coverage policies are not set nationally, but are established regionally by the decisions of the fiscal intermediary. Medicare + Choice plans are required to consider covering any service that is covered under fee-for-service, subject to medical necessity. If a national coverage policy has not been set, the plans are governed by the decisions of the local fiscal intermediaries, which can differ. As an example, Medicare + Choice plans in California must consider covering proton beam therapy for prostate cancer because the state's Medicare fiscal intermediary had ruled it was covered on a fee-for-service claim. Plans outside of California, however, are not required to consider covering proton beam therapy because their fiscal intermediaries have not made a coverage determination.

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[7] However, a large literature has documented significant practice pattern variation across the country.

4.8 External Influences on Coverage Decisions

4.8.1 Public Relations and Liability

Although the plans we interviewed generally aspired to evidence-based coverage decision making, nearly all cited instances in which this process had been circumvented. A number of plans described cases in which their coverage decisions were influenced by intense media scrutiny, public relations concerns, and liability fears. This was particularly palpable in California, where there had recently been a record-setting judgment against a plan (not one of those interviewed). It was also in the forefront of discussions in Seattle, where there had been a spate of negative publicity surrounding the refusal by two plans to cover treatments that they considered to be experimental (one for a patient with multiple sclerosis, the other for a patient with brain cancer). In both cases, the plans ultimately reversed their coverage denials, although the justifications for these decisions sought to avoid setting a precedent for future decisions.

Generally, technologies that raise significant liability or public relations concerns are referred from TA/medical policy committees to high-level plan administrators for review. When these reviews overturn the policy recommendation of the TA/medical policy committee, the adopted policy is generally less restrictive than the one initially proposed.

4.8.2 Consumer and Provider Demand

Plans also noted that they face considerable pressure from patients and providers. They expressed concern about the level of demand for new drugs generated by direct-to-consumer advertising. Many plans cited Claritin as an example, noting the use of television and magazine advertisements, as well as advertisements on public transportation and even airline name tags, to promote the drug. Although not all plans included Claritin on their formulary, it was difficult to make an independent coverage decision in the face of strong consumer demand.

Providers may also generate demand. Plans in California cited the aggressive marketing strategy of a hospital that had recently purchased a proton beam therapy machine. Plans may find it difficult to deny coverage when there is a strong physician advocate. For example, at the urging of a local neurosurgeon, a plan in Seattle had recently covered gamma knife surgery for a metastatic brain tumor although they did not believe the technique was of proven efficacy for this indication. Pressures from providers are not limited to life-threatening conditions. Some plans noted that they covered thin prep pap tests, despite the high potential cost impact and questionable cost effectiveness relative to conventional pap smears, because they did not want to antagonize the provider community.

Patients with serious illnesses increasingly take a proactive stance with regard to their treatment. Rather than relying on their physician's recommendations, they actively research treatment alternatives through a variety of avenues, including advocacy groups and the web. One plan described a case in which a member with terminal cancer learned about a new treatment through the developer's website which, among other things, provided access to legal assistance to fight insurers' coverage denials.

4.8.3 Regulatory Environment

State regulations can also influence plans' coverage decisions. In California, two of the plans interviewed noted that, despite internal assessments which found it to be no more effective than existing treatments, a state mandate required them to cover proton beam therapy for prostate cancer in men under the age of 65. A ruling by the California Department of Corporations, which regulates HMOs in the state, forced Kaiser to reverse its original decision to exclude Viagra from its formulary. Massachusetts mandates coverage of infertility treatment, including *in vitro* fertilization. In Seattle, several plans noted that Washington State has an activist insurance commissioner who, they believed, had inappropriately inserted herself in discussions of plan coverage decisions. Washington also has a state-mandate process for appealing denials of investigational/experimental procedures.

Texas is a bellwether state for the impact of Patients' Bill of Rights legislation. In 1997 Texas enacted a law requiring external review of coverage denials based on medical necessity determinations. Texas is also the first state to allow medical malpractice suits to be brought against managed care plans. The younger, locally based plans in Houston appeared to be more influenced by the legal climate than the established, national plans we interviewed there. The local plans felt it was difficult to deny coverage based on medical necessity and they were reluctant to do so, while the national plans did not indicate a significant impact on their behavior. One of the plans noted that the external review process rarely comes into play—only 0.2 per 1,000 plan members had made use of the process in the past year.[8]

4.8.4 External Review of Coverage Decisions

External review of plan coverage decisions is a growing phenomenon nationwide. Thirteen states have implemented some form of mandatory external review (Pollitz, Dallek, and Tapay, 1998). Medicare has had external review of coverage decisions by managed care plans since 1989. A number of managed care plans around the country have voluntarily implemented provisions for external review and the American Association of Health Plans has recommended that its members adopt binding independent review programs. In addition, NCQA standards for 2000 require plans to have a process for independent review of appeals of coverage denials for medical necessity.

One of the plans interviewed noted several advantages to having an external review program: (1) it adds objectivity to the decision making process and may provide information on cutting edge technologies that the plan does not have internally; (2) it is beneficial for risk management; and (3) it is good for public relations. While plans perceive benefits to these programs, the costs are relatively low—only a small number of cases are ever brought for external review and the cost per case is relatively low. According to the contractor that provides external review for Medicare, they hear 2.5 to 3 cases per 1,000 enrollees. However, this is substantially higher than the review rates for non-Medicare plans in states with mandatory review.

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[8] Texas' external review does not include Medicare, which has its own review process.

There are two main reasons for Medicare's higher review rate. First, Medicare provides for automatic external review if a plan's internal review process does not overturn an appeal of a coverage denial. In contrast, the state programs require the member to proactively request an external review. Second, the Medicare program encompasses review of coverage denials for any reason, while state programs are typically limited to review of denials based on medical necessity. California's external review program is even more restrictive and is limited to investigational/experimental treatments for terminally ill patients. The Medicare external review organization estimates that only five to ten percent of their reviews involve expensive, high technology treatments for life-threatening conditions. The bulk are over issues such as denials of emergency room and out-of-area services, formulary disputes, durable medical equipment claims, rehabilitation treatment, and level of SNF care. About 40 percent of the Medicare cases involve clinical review.

External review programs can potentially effect plan coverage decision making in several ways. First, most obviously, they can overturn plan coverage decisions. However, the impact of overturns is inconsequential given the low volume of cases reviewed and the relatively low overturn rates. The Medicare external reviewer estimates that they uphold about two-thirds of plan coverage denials. The overturn rate in state-mandated external review programs is somewhat higher, ranging from one-third to two-thirds across the states (Pollitz, Dallek, and Tapay, 1998).

Second, plans may be more willing to adopt "tough" policies if they believe the external review process provides them with protection in the event of a lawsuit. In practice, the import of external review for plan liability appears to be minimal. One of the external review organizations that we interviewed stated that they had never been asked to testify in court and were not aware of any cases where their ruling had been a factor in an award. The other noted that less than 5 cases per thousand of those they review proceed to litigation. In those that do, the external review organization will testify in court and they are not aware of any judgments that were contrary to their reviewers' findings. Of course, external review may provide an indirect protection by deterring lawsuits.

Finally, external review can have a sentinel effect on plan coverage decisions. State regulators have observed changes in health plan behavior following the implementation of mandatory external review programs (Pollitz, Dallek, and Tapay, 1998). The Medicare external review organization also noted that word of their decisions spreads among the Medicare + Choice plans, which sometimes adopt coverage policies that mimic the language in the review organization's decision.

4.8.5 Economic Conditions

Economic conditions can also influence the restrictiveness of plan coverage decisions. Plans across the country stressed that during the current economic boom, purchasers have little interest in cutting benefits. Growth in managed care enrollment has come in the more loosely organized segments of the market, such as IPA model plans, PPOs, and POS options. It is more difficult to enforce coverage policies in these looser arrangements. Indeed, one plan attributed the substantial increase in their technology assessment activities and the growing number of medical policy guidelines to their transformation from a staff model plan to a mixed staff, group, and IPA model. A group model plan noted that as a result of their closed organization, they relied less heavily on medical policy guidelines.

It should be recognized that our study took place under unusually robust economic conditions Although plans were not completely insulated from concerns about rising costs, they were not facing substantial pressures from purchasers to reduce costs. To the contrary, in many areas employers and consumers were encouraging plans to adopt less restrictive policies. Nonetheless, it is certainly possible that MCOs could be forced to adopt greater limitations on coverage in the face of a downturn in the economy.

4.8.6 Competitors' Policies

Interestingly, competitors' policies appear to have little impact on coverage decision making. Most plans believed in the integrity and objectivity of the process they used to make decisions and did not feel they should be swayed by other plans' policies. In addition, plans are not likely to explicitly solicit competitors' policies during their decision making because of antitrust concerns. Nonetheless, some interviewees noted that their provider panel will let them know if they are out of step with their competitors.

None of the plans interviewed viewed covering specific technologies as a marketing strategy. Beneficiaries generally do not select a plan based on a particular technology. Those that do are likely to be undesirable from a risk selection perspective. On the other hand, plans are concerned about public relations and do not want to be perceived as far more restrictive than their competitors. In sum, plans seek to look similar to their competitors and, in practice, most feel that they do.

4.9 How is Utilization of Technology Controlled?

It is difficult to enforce medical policy guidelines that involve medical necessity criteria. Medical necessity criteria are often based on complex diagnostic indications and treatment history. These types of criteria cannot be incorporated in an automated claims review process. As a result, plans generally do not monitor enforcement of their medical policy guidelines directly, although there is typically an understanding that providers wishing to order very new or expensive treatments will consult with the plan in advance to ascertain whether the service will be reimbursed. However, several plans noted that it is difficult to control "off-label" use of technologies that have been approved for limited indications. As one respondent put it, they can only monitor enforcement if violations of the guidelines "reach a certain level of noise." For this reason, one plan voiced skepticism about the usefulness of medical guidelines and considered covering a treatment subject to medical necessity tantamount to blanket approval.

Plans may use prior authorization or utilization review for some technologies to ensure that their policies have been implemented appropriately. However, plans report that these audit mechanisms are labor intensive and prohibitively expensive to use on a routine basis. In addition, providers view them as intrusive and onerous. As a result, our interviewees say they are reluctant to use these control mechanisms and they are typically reserved for a select set of technologies with low volume and very high unit costs (e.g., bone marrow transplantation, Ceredase for Gaucher disease).

Given the difficulty of directly monitoring enforcement of their technology coverage decisions, plans must use a variety of indirect mechanisms. One of the most important is provider education. Plans disseminate medical policy guidelines to their provider panels to educate them about approved standards of practice. As discussed previously, national plans have the additional challenge of educating their local affiliates about the proper implementation of medical policy guidelines. Drug formularies are also viewed as a tool to educate providers and members. Indeed, one plan noted that despite having an open formulary (i.e., one that applies the same copayments to formulary and non-formulary drugs), 86 percent of prescriptions are written for drugs on the formulary. Plans also may profile physician practice patterns, such as their prescribing patterns or use of certain procedures. In general, it appears that provider education is more easily accomplished within the tightly organized forms of managed care, such as group and staff models plans.

A second technique is off-loading risk to providers. In its most extreme form, providers are globally capitated and are paid a percentage of the plan's premium. Global capitation minimizes the need to monitor provider behavior because they have internalized the plan's incentives. Although they still develop medical policy guidelines, plans that globally capitate their providers are no longer concerned with monitoring whether providers deliver non-approved services because the plan is not at risk for their cost. However, patients can appeal treatment denials by the physician group to the MCO. Thus, the MCO's role becomes one of monitoring treatment denials and hearing appeals. Similarly, plans that use bundled hospital payments such as DRGs or per diems have limited interest in the specific technologies used during the course of an admission (although, depending on the payment method used, they are concerned about the need for an admission, length of stay, and readmissions).

While increasing risk-bearing by providers would seem to be a logical progression in the evolution of managed care, there has been a backlash against it. First, there are concerns that it creates a conflict between provider and patient interests. Second, it requires large groups with sophisticated management capabilities. This capacity has often been provided by entities such as physician practice management corporations (PPMCs). However, the dissolution of several PPMCs in recent years has led to significant instability among large physician groups. One of the plans interviewed, which historically had aggressively pursued global capitation contracts with its providers, was moving away from this due to the instability in their provider network caused by the failure of several physician groups in their market area. Finally, providers are less enthusiastic about accepting substantial risk than they have been in the past. This is particularly true in the Medicare market, where providers have found it difficult to generate a profit under their risk-bearing arrangements.

Plans also use beneficiary cost sharing to control use of covered technologies. This is most often applied to pharmaceuticals through the plan's drug formulary. There are several variants on drug formularies. Some plans use restrictive formularies and only cover those drugs that are specifically listed. Others cover non-formulary drugs, but impose substantially higher copayments to discourage their use. The structure of copayments in drug formularies is discussed in greater depth in Chapter 5.

4.10 Interaction with Hospital Decision Making

Hospitals have traditionally been the most important locus for the adoption of high cost new technologies. Teaching hospitals are particularly critical, because they are often the first adopters of new technologies. Many of these technologies that are first introduced in academic medical centers, perhaps as part of a clinical trial, will eventually diffuse to community hospitals. While their role has been somewhat reduced with the increasing emphasis on ambulatory care, hospital purchase decisions continue to play a key role in the diffusion of new technologies.

Traditionally, physicians have been the main drivers behind hospitals' technology investment decisions and the key decision makers. If there was a strong physician advocate and the hospital's budget could support it, hospitals faced few disincentives to invest in technology under traditional fee-for-service reimbursement. Indeed, powerful financial incentives encouraged continual investment. The availability of technology played a central role in competition with other hospitals in the market for patients. More fundamentally, hospitals used technology to compete for physicians, who are the primary source of their patient base.

The growth of managed care could potentially impact hospital decisions to invest in new technologies in several ways. First, if managed care constitutes a major portion of its patient base, a hospital may be reluctant to invest in a technology that is not covered by the plans with which it contracts. Second, bundled payment arrangements (e.g., capitation, DRGs, per diems) can create disincentives to invest in new technologies if the hospital does not receive any additional reimbursement for them. Third, discounted payments constrain the hospital's financial resources and limit the funds available to invest in new technologies. Based on our conversations with hospitals, however, it appears that managed care has had little effect on the fundamental forces that encourage investment in new technologies. The greatest impact is felt in markets where managed care dominates the market. Even in these areas, the effect is observed more at the margins rather than as a fundamental shift in the forces that drive decision making.

Physicians remained the driving force behind technology adoption decisions in all of the hospitals that we interviewed. Most investment decisions are precipitated by a member of the hospital staff who becomes interested in a new technology. A committee dominated by physicians votes on these purchase decisions. Of course, the committee often faces requests that exceed its budget, in which case physicians must compete against each other to have their project funded. One hospital noted that the outcome of this process is often determined by a physician's power within the department. If a purchase is small enough to be accommodated in a department's regular capital budget, the decision may be made at the department level. Larger purchases, requiring a substantial capital investment, would be made on a hospital-wide basis and involve the hospital administration (e.g., the finance department, the Board of Directors).

Physicians play a particularly dominant role at academic medical centers (AMCs). One AMC noted that they felt compelled to invest in any new technology that their physicians identified as necessary to remaining at the forefront of the areas where they are preeminent. Another AMC stated that they virtually always purchase technologies proposed by their affiliated medical school. This hospital had plans for an investment of over $100 million in new cancer research programs that had been advanced by the medical school. However, respondents at an AMC in a high penetration market area described an acute tension between the financial constraints imposed by managed care and its mission as a research institution to advance medical technology. This hospital had instituted a Value Analysis Committee in the past year, whose role is to evaluate new technologies. The committee's reviews take into account safety, efficacy, and cost.

Managed care has not changed hospitals' view that technology provides a competitive edge. Several hospitals noted that having technology is key to attracting contracts with

MCOs. One hospital felt the availability of new technology positioned it as a superior player in the market that all MCOs needed to include in their networks. Similarly, MCOs may need to include AMCs in their networks because of their prestige. On the other hand, a fully capitated physician group in a highly competitive market indicated that they do not contract with "A list" hospitals because of concerns about adverse selection. A community hospital said that they needed the full range of services within their hospital system in order to secure contracts; however, as a result of the financial constraints imposed by managed care and other payers, they did not try to have every technology in every hospital.

Hospitals continue to view technology as sources of new business. One hospital interviewed had recently invested in a gamma knife (one of a handful in the nation), requiring an initial $3 million investment and an additional $1 million per year to operate. The hospital viewed it as a profitable operation that attracted business from across the country. Indeed, the hospital's main competitor in the market was also planning to purchase a gamma knife. Thus, hospitals are driven by a double imperative—they seek both the technologies that their competitors have and, at the same time, technologies that will differentiate them from the competition.

The coverage policies of MCOs (and, indeed, of commercial insurers generally) do not play a major role in hospital technology investment decisions. One hospital said that they decide to adopt a new technology and "figure out how to get it covered by insurers after the fact." Their primary concern is Medicare FFS coverage policy based on the assumption that if Medicare covers a device or procedure, other payers will follow suit. One hospital did describe a process for making technology purchase decisions that takes into account payer payment policies (is it covered and, if so, the payment level).

The hospitals interviewed had a variety of reimbursement arrangements with MCOs. Most common are per diems, although some contracts use DRGs and, rarely, capitation. Some tertiary care hospitals continue to receive discounted FFS payments, at least for referral services. While hospitals are concerned about the payment system used, in this respect MCOs are viewed no differently from other payers, especially Medicare. Thus hospitals are concerned about the cost of additional tests for which they do not receive additional reimbursement or costly new procedures that are not recognized with higher per diem payments or a new DRG. Hospitals attempt to protect themselves by negotiating carve-outs or add-ons for certain technologies or by including stop-loss provisions or outlier payments in their contracts with MCOs. However, they are not always able to do this. Some hospitals noted that they respond to payment reductions by cutting overhead costs and reducing length of stay (clearly a responses to DRGs, not per diem payments), but not by cutting technologies.

Hospitals acknowledged that discounts negotiated by MCOs have the potential to restrict technology adoption by limiting their budgets. Although it was not universally the case, several of the hospitals interviewed had not yet faced serious financial constraints. Some were operating with very high occupancy rates. Others had been able to negotiate favorable contracts with MCOs because of their competitive position in the market. For others, managed care was still only a minor share of their patient base. However, hospitals in heavily penetrated markets and community hospitals appear to be more affected.

4.11 Interaction with Decision Making by Large Physician Groups

Some MCOs, particularly in mature managed care markets, off-load a substantial degree of their financial risk by fully or partially capitating providers. This practice is especially prevalent in California. Provider groups that accept capitation range from primary care groups, to large multispecialty physician groups, to integrated delivery systems that incorporate physicians and hospitals (e.g., PHOs). From the plan's perspective, these capitation arrangements have two main advantages: (1) they align provider incentives with those of the plan;[9] and (2) monitoring utilization becomes less important because the plan is no longer at risk for individual services. From the provider's perspective, accepting capitation offers complementary advantages: (1) the group reaps the rewards from any savings generated through reductions in service costs; and (2) plans intrude less in their practice patterns. These risk arrangements, in essence, push the technology coverage decision back a level to the providers. As one interviewee put it, medical necessity decisions are a "hot potato" that has been thrown into their lap.

Physician groups generally have fewer resources to do technology assessments than MCOs and have more rudimentary processes. Primary care groups, for example, are not qualified to assess esoteric new technologies used by specialists. For the most part, coverage policies are not set proactively, but are made in response to patient or physician requests. Two of the groups interviewed had committees to research new technologies and develop guidelines, while the others had no such formal structure. The plans that do not have a decision making structure generally follow the policies of the plans with which they contract. One said that they occasionally provide an uncovered benefit if they believe it is cost effective to do so. The other reported that they do not withhold necessary therapies, regardless of the plan's coverage policy. The plans with an internal decision making structure rely mostly on surveys of insurer policies or the expert opinions of affiliated specialists in making their coverage decisions. The groups that developed their own treatment guidelines and formularies contract with many MCOs (as many as 15 or 16). While it is easier to have a single set of policies than to track those of all the plans they contract with on a case-by-case basis, they face the inevitable problem that their decisions sometimes conflict with MCO policies.

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[9] In California, the Knox-Keene Act precludes physician groups from bearing full risk for inpatient care. As a result, the incentives of plans and providers are less perfectly aligned than would be inferred from the relatively widespread adoption of physician risk-bearing arrangements in the state.

While risk-bearing physician groups are free to cover any services not covered by the MCO, they are also required to cover all services that the MCO covers. As noted earlier, under the capitated arrangements, the primary role of the MCO is to monitor treatment denials and hear appeals. Capitated groups chafe under this arrangement, which allows MCOs to overturn their denials while bearing none of the financial risk. One group objected to "insurers practicing medicine," although they rarely have their denials overturned. Another expressed resentment that they might be forced to cover services that they do not consider cost effective—overturning a denial makes the MCO look like good guys and it costs them nothing, but it comes "right out of the group's pockets" under capitation. Of course, MCOs face an analogous problem, which leads them to shift risk onto providers.

Some groups were of the opinion that MCOs should retain the risk for high cost new therapies because they have a wider population base across which they can spread the financial risk. Depending on the number of lives covered by a physician group, a single high-cost case could be devastating. Because they believe physician groups are suited to handling "service" risk, but not "insurance" risk, they should only be at risk for managing therapies when they become routine and their costs are predictable. In some cases, MCOs offer reinsurance, special pools for high cost cases, or other cost sharing to insulate providers from financial risk to some extent. Over time, however, disputes arise as high cost technologies become routine and MCOs press to include them in providers' capitation payments. One plan described a conflict with MCOs over inclusion of kidney transplants in the capitation rate.

4.12 Summary

With few exceptions, the managed care plans interviewed had formal processes for setting technology coverage policies. Plans usually only set policy for a small percentage of the procedures and devices that come on the market, targeting those that are high cost or controversial. Drugs are assessed during the process of setting the plan formulary. The technology assessment process is clinically oriented and typically does not explicitly consider cost. Price is more often a consideration in setting drug formularies, however. Plans rarely conduct true cost-effectiveness analyses and instead focus on safety and efficacy.

With the exception of investigational/experimental therapies, the end result of the assessment process is only rarely a blanket policy of refusing to cover a technology. More commonly plans establish medical necessity criteria for its use. However, these criteria may be difficult to enforce routinely and plans can find it difficult to restrict use to the limited approved indications. Plans also face numerous external pressures that make it difficult for them to deny coverage of technologies. In particular, they cite an explosion in consumer demand for specific technologies.

We found that the level of managed care penetration in a market affected coverage policies far less than expected. We also did not observe important differences between policies in Medicare and commercial products. In addition, insurers that offered both managed care and indemnity plans used identical coverage policies across product lines.

5

Case Studies of Benefit, Premium, and Cost Sharing Determination in Managed Care Organizations

5.1 Introduction

Benefit, premium, and cost sharing policies are important aspects of managed care decision making that affect the services plan enrollees receive and their out-of-pocket costs for these services, as well as the rate of medical cost inflation. Benefit offerings and cost sharing requirements are alternatives to technology coverage policies that plans can use to control health care costs and technology usage. This section reports findings of our interviews with managed care plans about how they determine benefit offerings, premiums, and cost sharing levels. Section 5.2 discusses benefit determination, with subsections on Medicare and on commercial benefits. Section 5.3 discusses determination of premiums and cost sharing, again with subsections devoted to Medicare and to commercial premiums and cost sharing. Section 5.4 considers the process of making benefit, premium, and cost sharing decisions, and how it relates to the technology coverage decision making process described earlier in this report.

5.2 Benefit Determination

5.2.1 Medicare Plans

Medicare + Choice plans all offer the standard (traditional fee-for-service) Medicare benefits, as they are required to do. They decide on what additional benefits, if any, they will offer beyond the standard Medicare package. The most important and costly additional benefit that is sometimes offered is prescription drug coverage. Other commonly offered additional benefits are hearing exams and aids, eye exams and eyeglasses, dental exams and cleaning, preventive medical services/annual physicals, and transportation to and from medical appointments. These additional benefits may be subject to limitations (e.g., the drug benefit may be capped at $600 per year) and cost sharing (e.g., $10 copayment for 30 days' supply of drugs), which are discussed further in the section below on cost sharing determination. A single managed care organization may offer more than one Medicare + Choice plan, with different benefits, premiums, and cost sharing.

Four factors are most important in determining Medicare supplemental benefit offerings:

- the Medicare county payment rate;
- the price at which medical services can be purchased;
- competition with other MCOs, and with traditional FFS Medicare/Medigap; and
- adverse selection.

Medicare Payment Rate. Historically, Medicare paid MCOs 95 percent of the estimated per capita cost of FFS Medicare in a county, adjusted for demographic risk-rating factors (age, sex, etc.), the so-called Adjusted Average Per Capita Cost, or AAPCC. The 1997 Balanced Budget Act (BBA97) decoupled Medicare MCO payment rates from the AAPCC, basing them on complicated update factors applied to the 1997 AAPCC baseline.

BBA97 also mandated the introduction of health-based risk adjustment of Medicare capitation rates by January 1, 2000.

Geographic variation in the county Medicare rate is a major influence on the level of supplemental benefits offered. For example, the AAPCC has historically been more generous in Los Angeles than in Northern California or San Diego, so richer Medicare supplemental benefits are offered in Los Angeles than in other parts of the state. The higher Los Angeles rates also made that market more profitable and attractive for entry of Medicare MCOs, so many plans entered the market and it is highly competitive. In Seattle and Portland, Medicare's payment rate is low, and few plans include drugs in their zero premium offerings.

Typically, plans project their Medicare managed care revenue, which is in part a function of the Medicare per capita payment rate. They then subtract their estimated expenses for the standard FFS Medicare benefits such as hospital and physician services. What remains is available to cover the cost of additional benefits, marketing, and profit margin. When the Medicare payment rate is higher, they have more funds available to offer additional benefits. They offer supplemental benefits because competition forces them to, or they are non-profits who must as a general rule spend their revenues. Through its 'Adjusted Community Rate' process, HCFA also requires MCOs to convert excess revenues into additional benefits.

If Medicare's payment rate is constrained, supplemental benefits are reduced. Plans are affected by the growth rate of payments versus the growth rate of medical costs. In the few years prior to 1997, for example, increases in payments and costs had been in line at roughly 4 to 5 percent in the Los Angeles market, according to one respondent. Since 1997, for example, the BBA has constrained payment increases to 2 percent in high payment areas such as Los Angeles and Boston, while costs, especially for drugs, have rapidly escalated nationwide. Therefore, benefits are being constrained in high payment markets, and in some cases, plans are exiting certain counties or markets. Also, the introduction of health-based risk adjusted is expected to eventually cut MCO payments overall by 4 to 7 percent, although it is being gradually phased in. Plans typically will reduce, but not eliminate, drug benefits in response to constrained payments. They will also eliminate or make less generous non-mandatory benefits such as hearing, vision, transportation, etc. Another option is to raise premiums and copayments to cover shortfalls (see Section 5.3 below).

Cost of Services. The other element of the payment/cost equation is the cost at which medical services can be purchased in a given market. For example, the hospital market in Los Angeles is more competitive than in Northern California (one hospital chain dominates San Francisco, another dominates outside San Francisco). This allows managed care organizations to obtain greater discounts from hospitals in Los Angeles than in San Francisco. Therefore, more gross profits are available in Los Angeles to fund supplemental benefits. Through competition, the higher gross profits are translated in more generous benefits in Los Angeles than in San Francisco.

Competition. Medicare MCOs compete with each other, and with the combination of traditional FFS Medicare and Medigap supplemental policies. Medicare beneficiaries tend to enroll in MCOs primarily for economic reasons. That is, they compare the combination of benefits, premiums, and cost sharing they can obtain from MCOs to what is available from traditional Medicare plus Medigap. More affluent beneficiaries tend to prefer the provider choice allowed by traditional Medicare plus Medigap, and they can afford to pay the often high Medigap premiums that allow them to retain this choice. Thus, in many markets, Medicare MCOs appeal most to Medicare beneficiaries of modest economic means, who are willing to sacrifice provider choice to save money. But plans must offer an attractive enough benefit package to lure these beneficiaries from FFS Medicare. Typically, drug benefits offered for a zero premium is seen as very attractive to beneficiaries.

Medicare beneficiaries also compare benefits, premiums, and cost sharing offered by the various MCOs in a market. In many markets in which we interviewed (which were exclusively large urban markets), interviewees stated that the Medicare managed care market was highly competitive. Thus, rather small shifts in benefits (or in premiums or cost sharing) could result in substantial shifts in market share. Some MCOs do focus groups or other forms of research to determine what benefits beneficiaries are most interested in. Prescription drugs are usually cited as the most desired benefit, followed by vision, dental, and hearing aids. Plans offer the benefits that they think will attract the most enrollees, subject to concerns about adverse selection (discussed below). They want to gain market share to exploit economies of scale, and in the case of small plans, to obtain the critical mass (minimum efficient scale) of members necessary to be financially viable.

Plans also trade off the efficiency of marketing expenditures versus adding benefits in attracting beneficiaries. If payment rates are constrained, marketing expenditures, as well as benefits, will be reduced. Plans promote their Medicare managed care offerings most heavily in areas where they are most profitable. So if constrained payment rates reduce the profitability of Medicare managed care, it will be promoted less heavily and grow more slowly.

Adverse Selection. Although competition tends to force plans to add benefits to attract enrollees, they want to avoid attracting sick, and therefore, high cost enrollees. Plans add benefits that they think have wide appeal or target healthy beneficiaries, and avoid benefits that appeal specifically to chronically ill beneficiaries. Thus, plans do not add benefits like 'extra intensive cancer care' or 'AIDS specialty care.' Instead the supplemental benefits are drugs, vision, hearing, fitness center discounts, etc. MCOs follow this same philosophy in building their provider networks, which are intended 'for the many' needing primary care, not 'for the (sick) few'. While plans may desire a general reputation for quality care and affiliation with high-quality or technologically advanced providers such as academic medical centers, they are not anxious to be known for, nor do they market, having 'excellent cancer care', or 'excellent AIDS care.'

Thus, there are two forces tending to enforce uniformity of benefits among plans in a given Medicare managed care market. Competition requires plans to have a similar benefit package to be equally as attractive as their competitors. Adverse selection requires that a plan not have a benefit package that is richer or more attractive to the chronically ill than its competitors. Plans typically have a drug benefit because it is very attractive to beneficiaries, but in many markets they cap it, because they do not want to become a magnet for beneficiaries who have high drug costs (and also tend to have very high nondrug costs).

In some markets, the forces of competition and adverse selection have resulted in basically a single, uniform benefit offering among all competitors. In Boston, for example, this is true. In the mid-1990s in Boston, plans typically offered two plans, a zero-premium, no drug plan, and a plan with unlimited drug coverage for a premium. The latter was mandated by the state. But BBA97 preempted state regulation of Medicare managed care plans. One Boston-area plan then eliminated its unlimited drug benefit option, and the other area plans felt compelled to follow suit. By 1999, Boston area plans had switched to a single zero-premium, capped drug benefit offering. Boston MCOs wanted to retain a drug benefit as a competitive inducement to attract beneficiaries. But despite intense political pressure, they refused to maintain an unlimited drug benefit because they did not want to attract an adverse selection of expensive beneficiaries. Post-BBA97, the Boston Medicare managed care market is also evolving in the direction of dropping state-mandated services because of adverse selection.

In other markets, the equilibrium is different. In Los Angeles, the two leading plans offered an unlimited drug benefit at the time of our study (1999). This may be related to the high profitability of the Los Angeles market, which is able to support these generous drug benefits. In addition, discouraging access to drugs through high copays is contrary to the philosophy of one of the leading plans that drugs are a cost effective treatment modality.

This plan feels that it can manage drug costs effectively through such means as a closed formulary, which allows it to offer a generous benefit. Very large plans in a market may be less subject to adverse selection, and their decision making may be more dominated by competitive considerations. Many smaller plans in Los Angeles do have drug benefit caps. They may be more concerned with being overwhelmed by adverse selection, or they might be attempting to 'cherry pick' healthier enrollees.

In Chicago and other markets, some plans do offer more than one benefit package/premium combination. Typically, the 'premium' or 'Gold' package offers reduced cost sharing and higher drug caps for a nonzero premium. Why multiple drug coverage options are sustainable in, say, Chicago without a state mandate but not Boston is a bit of a mystery. The Chicago market is larger and more balkanized than the Boston market, which may ameliorate adverse selection. Also, the extra premium charged for the additional benefits in Chicago seems high relative to the actuarial value of the added benefits. Thus, the Chicago plans may be anticipating, and accounting for, considerable adverse selection in their plan pricing.

5.2.2 Commercial Plans

Benefit determination for commercial plans is quite different depending on the size of the employer. The small employer (less than 50 employees) market has similarities to the individual enrollment Medicare market. To reduce marketing and administrative costs, as well as adverse selection, MCOs offer one or a few standardized benefit plans to small employers at a fixed premium. The small group/individual market is often heavily regulated by states (see below).

In the large employer market, the employer is a very important actor. Large employers demand, and receive, customized benefit packages. Insurers present employers (or their benefits departments) with a menu of benefits and their (actuarial) costs, and the employer chooses the benefit package. Administratively, choice is accomplished through the use of 'riders' to a basic insurance policy specifying additional benefits to be covered and the associated additional premium. MCOs have attempted to introduce standardized policies to rationalize the large employer market, but employers have resisted. The exception is national employers and unions, who are asking for the same benefit package across areas. Historically, benefit decisions were made in each local market, but now some insurers are introducing more centralized decision making. Centralization responds to the demands of national employers for standardized benefits and at the same time is expected to result in administrative savings.

Although large employers have considerable discretion over benefits, it is generally restricted to perceived 'lifestyle' therapies (e.g., Viagra) or services outside the core of acute care, such as physical therapy, speech therapy, occupational therapy, infertility, dental, contraception/family planning, chiropractic, vision, alternative medicine, mental health, durable medical equipment, and podiatry. Basic acute care, physician and hospital medical therapies, even if very expensive, are covered in all products, with only rare exceptions.

Coverage for prescription drugs can also be optional, although the vast majority of employers in most markets choose it. Some insurers are concerned, however, that rising prescription drug costs may cause more employers to drop it. One large Chicago employer does not 'believe in' home health care, and it is not covered in its insurance policy.

Interviewing employers about their benefit decisions was outside the scope of this project. However, MCOs report that employers choose benefits to maximize their attractiveness to potential employees. Health care benefits can be an important recruiting/retention tool in a very competitive labor market. Since the economy is currently very strong, and employees are well off economically, they are demanding generous benefits and more freedom of provider choice. Employers feel compelled to satisfy these demands to remain competitive in hiring. In particular, less restrictive 'Preferred Provider Organization' (PPO) type plans have gained market share in many areas at the expense of more restrictive managed care plans. Employee demand also leads to regional variations in benefits, such as acupuncture being offered in Seattle.

Employers generally choose broad classes of benefits, such as 'physical therapy', or 'home health services', not specific technologies. Contracts specify that MCOs will cover all 'medically necessary' services, not specific technologies. Actuarial prices are established for these broader service types; costs of specific technologies are absorbed within these larger categories. MCOs see part of their value added to employers to be determining what services are 'medically necessary'. Rarely, a specific expensive service, such as solid organ transplants, might be explicitly covered or not in an insurer's contract with an employer.

However, one plan predicted that rising costs of new technologies might lead insurers to offer "skinnier" benefit packages with more coverages offered as riders. For example, one plan is considering adding a rider for sexual dysfunction in response to a state ruling requiring them to cover Viagra.

In general, the degree of cost sharing and provider choice varies more across health insurance products than do benefits covered. Employers may choose a $5 or $10 office visit copay for their employees, or a closed or open network plan, but they do not choose to cover specific technologies. Employers may also offer a menu of insurance options to employees, varying along the dimensions of premium cost (to the employee), provider choice, benefits, and cost sharing, and let the employee decide. But, to avoid adverse selection, some insurers will only let employers offer one option from that insurer to their employees.

In some states, legislative mandates for coverage affect benefit offerings. Mandates only affect insurance plans over which the state has regulatory authority, not self-insured plans, which are federally regulated under ERISA. Self-insured employers may request carve outs of state-mandated benefits (e.g., *in vitro* fertilization) from their plans. States may require standardized benefit plans for the small group and individual markets, as in California and Massachusetts.

5.2.3 Comparison Between Commercial and Medicare Benefits

The core 'medically necessary' acute care hospital and physician benefits are almost always the same in commercial and Medicare offerings. Some Medicare+Choice plans, which are exempt from state mandates, do not offer state-mandated benefits that are covered in commercial plans. Other than the core or state-mandated benefits, plans report that Medicare managed care benefits are often more generous than the typical employer-provided benefit plan. Medicare plans may have less cost sharing, and more 'non-essential' added benefits such as vision and hearing. This 'Medicare advantage' may be eroding somewhat, however, with BBA97 restrictions on growth in Medicare capitation payments.

5.3 Premium and Cost Sharing Determination

5.3.1 Medicare Plans

Premiums. The main factors driving Medicare + Choice premium levels are:

- the Medicare county payment rate; and
- competition with other MCOs, and with FFS/Medigap.

If the capitation rate is low in a county, a premium is more likely to be charged. Some plans in Massachusetts, for example, offer the same product over multiple county service areas, with a zero premium in high-rate counties, and a nonzero premium in low rate counties. Often Medicare payment rates differ more among counties than the difference in the cost of providing services. Shortfalls in low payment counties must be made up by premiums. Or managed care plans do not serve certain areas at all. For instance, Medicare's capitation rate is much lower in suburban Chicago than in urban Cook County, a much greater difference, the plans feel, than the difference in the cost of services. So most Chicago-area plans focus on Cook County, and managed care penetration in the suburbs is very low.

Premium pricing is important in attracting Medicare beneficiaries to managed care products. Beneficiaries are sensitive to premiums, and Medicare managed care plans often strive to charge no premium while offering additional benefits. These inducements are necessary to compensate beneficiaries for giving up the freedom of provider choice in FFS Medicare. Higher Medigap premiums in an area make it easier for MCOs to charge higher premiums for Medicare+Choice products since Medicare MCOs compete against the Medicare FFS/Medigap combination.

Medicare plans also compete against each other. If zero premium is the standard in a market, a plan is generally not competitive if it charges a premium. For example, one plan in Boston had a premium a few years ago, but was forced to drop it to remain competitive. Plans will strive to introduce more cost sharing, or reduce some benefits to retain a zero premium. A zero premium is a key means of attracting new enrollees. Cost sharing schedules, in contrast, may not be noticed until services are used. Moreover, limiting cost sharing may be most attractive to sicker beneficiaries, whom the plans are not eager to enroll. Plan offerings with a higher premium typically buy less cost sharing and/or better drug benefits (e.g., higher annual spending cap).

Cost Sharing. Traditional FFS Medicare imposes substantial cost sharing requirements on beneficiaries in the form of deductibles and coinsurance. For example, traditional Medicare Part B has a $100 deductible and 20 percent coinsurance above the deductible. Many FFS enrollees purchase supplemental Medigap policies to cover Medicare cost sharing.

All Medicare MCOs cover the deductible and coinsurance cost sharing requirements of traditional Medicare, substituting their own much more limited copayments. For example, in contrast to FFS Part B cost sharing, Medicare MCOs typically impose a $5 or $10 payment office visit copayment. Caps on prescription drug benefits can also be considered a form of cost sharing, i.e., 100 percent cost sharing above the cap.

The main factors driving cost sharing are:

- the Medicare county payment rate;
- competition; and
- cost control.

The first two factors—the capitation rate and competition—affect cost sharing in the same way as they affect premiums. Cost sharing is more likely to be higher in low rate counties, although the premium is more often adjusted than cost sharing. Beneficiaries are sensitive to cost sharing as well as to premiums. One plan we interviewed lost substantial enrollment when it raised its Medicare drug copay from $5 to $6. So plans strive to be competitive in their cost sharing levels.

The third factor—cost control—is unique to cost sharing. Cost sharing controls the plan's cost of services in two ways. First, costs of a given level of services are shifted from the plan onto the beneficiary. Second, cost sharing discourages utilization of medical services. Cost sharing is an alternative to coverage policy, utilization review, or other nonprice quantity restrictions in controlling costs. (Coverage policy can be thought of as an extreme form of cost sharing, i.e., enrollee cost sharing is 100 percent when a service is not covered.) As compared to coverage policy, cost sharing has the advantage of providing some coverage for services beneficiaries may desire, while also helping to control costs.

For example, all plans offering a drug benefit have faced the problem of rapidly escalating prescription drug costs. Various strategies have been adopted to reduce drug expenditures. But the main strategy many plans are using is a three-tier drug copayment structure. Details vary, but typically, the copayment is lowest for generic drugs, say $10 per 30 days supply, intermediate for 'preferred' or formulary brand name drugs, say $25, and highest for non-formulary brand name drugs, say $50. Physicians may be able to appeal a brand name drug's copayment if they feel it is medically necessary for their patient. Certain so-called 'lifestyle' drugs such as Viagra may also be put in the highest copayment category. If beneficiaries want non-formulary brand or lifestyle drugs, they can obtain them with some subsidy from the insurance plan, but they have to pay more out of pocket, controlling costs. In adopting this copayment structure, MCOs are partially abandoning their traditional primary reliance on nonprice means of rationing demand. Many are extending, or thinking of extending, cost sharing requirements to other areas, such as $50 for an emergency room visit not resulting in an admission, or imposing a deductible for hospital stays. Office visit copayments may also be raised.

Plans typically will increase cost sharing rather than eliminate a benefit altogether, especially an important benefit like drugs. An interviewed plan reported, for example, that it raised cost sharing to retain a drug benefit in a zero premium plan. Plans in some markets also offer 'premium' or 'Gold' versions of their plans where cost sharing requirements are reduced in return for a higher premium. Beneficiaries are then free to choose their preferred level of cost sharing/premium. But plans in some markets such as Boston have found that adverse selection makes it difficult to offer a 'high option' plan. Sicker, more expensive beneficiaries may disproportionately select high option plans, such that the premium necessary to break even is 'prohibitive'.

In general, plans attempt to balance the gains and losses in members and type of members from premiums, cost sharing, benefits, benefit caps (e.g., annual drug spending limits), and marketing. In the Boston area, for example, one plan has a lower annual drug spending limit, but no drug copays. Another plan chose to have drug copays, but a higher annual cap. These benefits, one of the plans reported, are 'actuarially equivalent'.

5.3.2 Commercial Plans

In general, the cost of purchasing medical services is the single largest factor driving premiums, both over time, and across markets. Plans must price their products to cover their costs. When large cost increases occur, such as the dramatic rise in drug costs in the mid-1990s, premiums will rise to cover these costs. In addition, premiums will tend to be higher in areas, such as Boston, that have high medical costs. Areas with high provider concentration/bargaining power, such as San Francisco/Northern California, will tend to have higher premiums, as MCOs pass through their higher cost of purchasing services.

As in the Medicare market, competition in the commercial market is an important factor determining premiums. Plans charge 'what the market will bear'. Concentration on both the insurer and purchaser sides can affect relative bargaining strength. For example, employer/purchaser buying groups are actively working to hold down premiums in some areas, such as Northern California and Boston. In other areas (e.g., Chicago), purchaser groups are weak or absent.

Premium cycles also affect rates of change in premiums. Plans in several market areas across the country reported that MCOs held down premium increases in the mid-1990s to gain market share. But medical costs continued to rise, faster than expected. Now MCOs will be forced into large premium increases to cover their costs.

In the commercial market, employers play an important role in determining cost sharing. MCOs will typically give employers a choice of several different cost sharing levels, with a lower premium for the higher cost sharing levels. So employers trade off premiums for cost sharing. As is true of benefits, cost sharing may be customized for large employers. Employers may also offer employees plans with different levels of cost sharing, letting them choose.

5.3.3 Decision Making Process

In contrast to technology coverage policies, decisions about benefits, premiums, and cost sharing are seen as 'business' decisions, not 'clinical' ones. Hence, benefit, premium, and cost sharing decisions are made by product line managers, marketing professionals, Vice Presidents for Medicare or government programs, and other 'business-oriented' decision makers. Usually there are different managers for the Medicare and commercial lines of business. These persons take into account the competitive environment vis-à-vis other health plans or insurers (including traditional FFS Medicare), beneficiary demand as perceived through marketing efforts, focus groups or other market research, cost of purchasing services from providers, marketing costs, and the regulatory environment.

In larger plans, there may be a formal committee that makes benefit, premium, and cost sharing decisions. This committee may include representatives of legal and regulatory departments. In small plans, especially small Medicare plans, the decision making process may involve only a few people and, thus, is more informal. In some plans, there is virtually no overlap between the plan managers who make technology coverage decisions and those who make benefit/premium/cost sharing decisions. The two are seen as separate realms. However, there seems to be a growing realization at some plans that more communication between the two decision processes would be desirable. In some plans, especially small Medicare plans, there is considerable overlap between the 'clinical' decision makers on technology coverage and the 'business' decision makers.

For example, in several Chicago-area plans we interviewed, one or a few business-oriented physicians led decision making in both areas. In a large California Medicare plan, a key physician sat on both relevant committees. In the large Boston Medicare plans, the decision makers in the two realms were different.

6

Case Studies of Device Manufacturers

6.1 Introduction

To fully understand the impact of managed care on the development and diffusion of new innovative technologies, staff at Health Economics Research conducted interviews with several major manufacturers of medical devices and pharmaceuticals. This chapter reports findings from our case studies of device manufacturers. The next chapter continues with a companion summary of comments from pharmaceutical manufacturers. Both chapters are organized around similar research questions with emphasis given in Chapter 7 to differences in the way drug research and marketing is conducted and how managed care might be affecting demand differently from devices.

Our primary goal was to gain a clearer understanding of how sensitive device manufacturers are to the spread of managed care, and particularly Medicare managed care, in the United States. However, in order to put managed care into context, we also asked device manufacturers about other factors that play a role in R&D decision making, including the impact of fee-for-service Medicare and forces outside the health care industry. Given that managed care was seen by respondents as a minor influence, some effort is devoted to understanding what factors are primary influences on R&D strategies and why managed care is of lesser importance. Among the questions addressed in this chapter are:

- What are the major underlying factors influencing device demand?
- What is the influence of basic science on spending for R&D?

- Who are the direct and indirect purchasers of technologies and why are the direct clients so important to manufacturers?
- In what areas do manufacturers perceive significant impacts of managed care on R&D?
- Why do manufacturers perceive managed care as having a relatively limited impact on the development and diffusion of technologies?
- What are manufacturer perceptions of the role of cost effectiveness analysis in managed care technology coverage decision making?
- What are manufacturer perceptions of the future of managed care?
- What are manufacturer perceptions of the importance of Medicare managed care?
- What were manufacturer perceptions of the importance of Medicare fee-for-service versus Medicare+Choice modes of payment?

The rest of the chapter is divided into nine sections that address each of the above questions. Unless specifically noted, all the observations come directly from interviewees. All comments have been paraphrased as accurately as possible. Hopefully, the substance, if not the precise phrasing, has been faithfully retained. No effort was made to empirically corroborate their statements and interpretations or to rigorously generalize to the universe of manufacturers. We do believe, however, that the sentiments of respondents likely extend to many in the device industry--especially for particular markets. Even if some impressions are not wholly accurate, the fact that they are held by major decision makers and analysts in large, sophisticated medical product firms is still important, for they form the rationale and motivation behind the way manufacturers behave. Absent perfect knowledge, perceptions are the foundation of current R&D strategies that determine the direction of technical innovation in medicine in the future.

6.2 Major Underlying Factors Influencing Demand for Devices

In order to understand how managed care influences R&D decision making, marketing, and the adoption and diffusion of new technologies, it is important to review the other key factors that manufacturers consider in their strategic planning. In addition to technology developments outside medicine, which are discussed in the next section, respondents listed five other primary factors.

Aging of the U.S. population. All respondents emphasized the importance of the aging U.S. population as a positive factor in product demand. Some firms tracked the shifting age distribution--especially the growth of the old old population. They monitored the vital statistics and health status statistics on illness incidence and prevalence in the population. Statistical data and trends of these kinds confirmed a growing market for their products. The predicted acceleration in the size of the aged population 15 years from now, while beyond most R&D cycles, was considered to be so large that firms today felt assured of a "guaranteed" market in the future.

Based on respondents' comments, we can distinguish between a direct effect of population aging on device demand versus a more indirect, long-term effect from the development of new technologies in anticipation of a burgeoning elderly population. We note that demographic trends have been assigned modest roles in health care spending by HCFA's Office of the Actuary over the last 35 years--about 10 to 15 percent of annual growth.[1] If new device (and drug) technologies increase the demand for health care, as many believe in the literature, then the aging of the population will have a growing "anticipatory" impact on health care cost increases. Health care spending may accelerate even faster than predicted based simply on forecasts of growth in the over-65 population as new technologies, developed in anticipation of the demand that will be generated by the expanding elderly population, enter the market over the next 20 years and widen the range of available interventions.

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[1] The estimate of aging effects on health spending is based on a weighted average of spending by age group. As the population ages, the population weights place more emphasis on the greater spending of the over-65 population.

New Illnesses. New illnesses, such as AIDs and Alzheimer's Disease, appear over time. These spur new diagnostic and treatment markets. Also, improved diagnostic tools permit clinicians to discover latent illnesses and risk factors that could not be detected previously and that might call for asymptomatic treatment. Furthermore, respondents did not limit their market to the U.S., but took into consideration the actual and potential health needs of other nations, including many illnesses that had been eradicated in the U.S.

International Markets. All the companies we interviewed had an international marketing force. In some cases, nearly half their sales were overseas. Manufacturer marketers we interviewed reported steady (and often dramatic) market increases internationally for their products. Respondents cited two reasons for the importance of international markets. First, other countries could provide a market for new technologies whose growth might be stifled in the U.S., primarily because of more stringent criteria applied by the Food and Drug Administration (FDA) than elsewhere. Second, respondents emphasized the potential size of overseas markets. The overseas market is growing faster in absolute terms, according to respondents, than the U.S. market. A one percent growth in the use of a particular device or drug in the U.S. constitutes many fewer patients than an identical percent increase in the rest of the world.[2]

We note that a growing global market has profound implications for R&D spending and development of new technologies. Technical innovation is becoming less constrained by the domestic market. Foreign demand provides an increasingly important source of revenue to support R&D and new technologies. Once available, these technologies may create their own demand in the U.S. market, as well as abroad. Thus, in forecasting future R&D and overall U.S. health care spending, modelers will need to take foreign demand factors into consideration.

Quality Assurance. Although outside the range of technologies that are the focus of our study, one respondent noted the new Joint Committee on Accreditation of Healthcare Organizations (JCAHO) audits of clinical information systems as a potential factor in raising the demand for certain technologies. JCAHO, and other review organizations, were expected to emphasize monitoring of quality assurance activities which, in turn, would mean even more administrative computer support.[3] It will also mean instantaneous electronic ordering of tests and drugs and scheduling procedures through computer networks.

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[2] Based on calculations by the authors, the U.S. constitutes about 5 percent of the world's population. The developed countries in Europe, Japan, Australia, Canada, etc., comprise about 1 billion people. If, under their generous, often universal, health insurance schemes 80 percent would be eligible candidates for new technologies, that makes a potential market of 800 million. The middle and upper classes in the developing countries with substantial purchasing power constitute about 5 percent of the remaining 4 billion persons, or 200 million persons. Thus, the total world market for new technologies may be roughly four times the size of the U.S. market (i.e., 1 billion versus 250 million persons in the U.S.).

[3] The desire for greater monitoring recently received more attention with published studies showing the high drug error rate associated with hospital care.

Technology Adoption Cycles & Public Policy. Many technology diffusion paths follow a classic curve with initial slow adoption, followed by rapid adoption, then market saturation, and, finally, a second generation of upgraded replacements. Most models of technology diffusion incorporate cyclic purchasing behavior into explanations of demand. One forecaster we interviewed claimed that the 1993-97 period was a "disaster" in terms of hospital-based demand for equipment. The primary reason given was the Clinton health care reform effort. Faced with a radical shift in how they might be paid, hospitals drastically reduced equipment purchases--especially of more established equipment. The result was a sizable jump in demand in 1998, followed almost immediately by another set-back due to Y2K and more provider uncertainty, this time due to concerns about the proper functioning of technologies already in place.

One respondent hypothesized that health reform and Y2K may have been so profound as to synchronize much of the provider investment in health technologies. Manufacturers can be thought of as producing two kinds of technology. One, generally dominant, set of technologies is widely diffused with minor upgrades over time, e.g., CT scanners. These established technologies are subject to adoption cycles in a somewhat predictable way depending upon the timing of their early "take-off" adoption phase in the past. The other type involves new technologies in their early diffusion phase, e.g., implantables, telephonic monitors. With thousands of devices on different adoption curves, the whole process usually is submerged into a general upward trend in industry-wide device demand devoid of obvious spending cycles. However, if large, exogenous "shocks" such as health care reform and Y2K suppress both kinds of diffusion (and replacement) for a number of years, then the adoption-replacement cycles of many technologies may become synchronized, creating the appearance of a powerful cyclic pattern rather than a general upward trend.

Adoption cycles created by large shocks to the industry have implications for linking technology to managed care and health spending. First, in periods of uncertainty, industry investment in new and old technologies will fall, resulting in lower cost inflation in the short run. This recession could have been correlated with the spread of managed care, with the misleading impression that the latter was a causal factor in depressing the spread of technology and health care spending. Second, once the uncertainty is removed, pent-up demand results in significantly greater spending on technologies of all kinds that, again, is not causally related to managed care. It may take some time before the cyclic effects dissipate and both technology diffusion and R&D investments return to a linear upward trend.

6.3 Influence of Science on R&D Spending

A hypothesized critical factor in the feedback effect of new technologies on health care demand and spending is the role of science and technology outside the device and drug industry. Technical change elsewhere in the economy, it has been argued, acts as a facilitator in the development of new health care technologies. Respondents were consistent in the emphasis they placed on "outside" technical change in justifying major increases in R&D spending. Not only did respondents highlight key external drivers of demand, such as the aging of the population, they also noted the growing opportunities to meet the needs of the population through adaptations of underlying scientific advances.

Implantables. The impact of enhanced computer speed, reduced size, and lower cost was said to permeate the health industry. This was true both for established technologies, such as laboratory equipment and pacemakers, as well as newly diffusing technologies, such as implantables. Neurological implantables are an example of the extreme portability afforded by computer miniaturization. Implantables deliver morphine, control back spasms, defibrillate erratic heart beats, infuse chemotherapy drugs in liver cancer patients, and control incontinence. Lower-cost implantables with controlled drug infusion open up the device market for congestive heart failure patients whose treatment is otherwise limited by organ supply. Micro-computer chips allow clinicians to manipulate organ and cellular behavior to prolong and improve the quality of life. They do so at great benefit to the patient by not requiring obtrusive external mechanisms and constant readmissions to hospitals for care; hence, demand for new technologies is increased.

Diagnostic Imaging. Smaller, high-powered computers and better magnets have also greatly improved the speed and clarity of diagnostic imaging. In 1985, the fastest computers could provide a single image every 20 seconds. By 1998, the rate was up to 15 images per second, a 300-fold improvement. Companies are now moving to molecular level spectroscopic imaging to provide the clinician with even more information.

Fiberoptics. Endoscopes and catheters have permeated medicine in the last 25 years. Attached to the end of the catheters are cameras, balloons with cutters, and drugs that unclog arteries and veins. Knees are scoped and cleaned out on an ambulatory basis; even gall bladder stones are removed by laparoscopic surgery. None of these devices would have been possible without technical developments in fiberoptics outside medicine.

Telemedicine. Remote diagnosis and treatment of patients has flourished in the last six to eight years. More and more, clinicians and health plans are managing patients remotely in several ways. Clinicians can download information from implantables sent transtelephonically to supplement standard patient data. Telemedicine also allows physicians to alter drug regimens, as well as patient visit schedules, remotely.

Biotechnology. The ultimate driver of the health care market may well come from genetic engineering. Enzymes exist for treating or diagnosing genetic diseases such as Gaucher's Disease and Tay-Sachs Disease. Cytogenetics includes amniocentesis testing for genetic abnormalities (e.g., Down's Syndrome) in fetuses. New surgical products improve wound healing adhesion to prevent scarring. Tissue repair using genetically produced biotissue can re-grow cartilage and improve joint function. Genetic diagnostic testing improves test accuracy. Fundamental investments in DNA and other genetic research may well eliminate whole ranges of diseases, e.g., cancer, heart disease. Finally, the human genotype project is believed by experts we interviewed potentially to be the biggest scientific advance in medicine since antibiotics and anesthesia.

6.4 Direct and Indirect Purchasers of Technologies

Hospitals and Physicians Are Key Direct Purchasers. According to our respondents, managed care plans were not often directly involved in the purchase of their products. For most medical technologies, the direct purchaser is the hospital or the physician practice.[4] Hospitals and physicians (and other providers like nursing homes and home health agencies) are considered direct clients by manufacturers. The hospital remains the main locus of technology adoption in the first instance. R&D directors cited academic medical centers (AMCs) as key to their business because they are most likely to be the first purchasers of innovative technologies, and because they are the leaders that other providers follow in adopting new technologies.

For *replacement equipment*, including x-ray machines, ultrasound machines, and patient monitors, hospitals are the main client. Respondents claimed that interest today is less in machine efficacy (e.g., marginal improvements in diagnostic performance) than in strict financial rates-of-return (e.g., number of tests at a fixed cost and price per test). For *new devices*, physicians play the lead role as they must decide on the efficacy of a novel device. Cardiologists were mentioned by a couple of respondents as being especially entrepreneurial and prone to adopt new technologies.

The growing number of specialists contributes to the demand for new technology. Familiar with their use and effectiveness, specialists will more likely recommend new technologies and drugs for both diagnosis and treatment. Specialist services are so complementary with technology, asserted one respondent, that the past growth in specialists assured a strong demand for the firm's products. Moreover, rapid technical change in a particular clinical area was believed to have a feedback effect, encouraging medical students to specialize.

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[4] Staff model plans that own their own facilities are an exception, although even in these plans individual hospitals and physician groups have some capital budgets at their own discretion.

Respondents emphasized that hospitals are far more price conscious than physicians. Unlike physicians, hospitals incur equipment costs for both inpatients and those treated in the emergency room and outpatient clinic. Physicians treating inpatients do not pay for expensive devices or drugs. Marketing to physicians providing ambulatory care almost always is keyed to CPT procedure codes, as most insurers still pay on a discounted fee-for-service basis. Fee-for-service physician payment requires a different argument than companies make to hospitals that have substantial numbers of patients reimbursed under capitated per diem or bundled DRG per case rates.

Managed Care as an Indirect Client. Manufacturers generally did not have managed care plans as direct clients, although they are increasingly becoming indirect, "virtual" clients by making coverage decisions and altering payment arrangements. Manufacturers face a confusing, and sometimes conflicting, array of incentive structures when marketing their products. Hospitals and physicians buy equipment usually in response to fee-for-service payment; managed care plans make decisions about covering new technologies in response to the incentives of full capitation. Marketers are challenged to develop different financial justifications for their products depending upon the client. The fact that managed care plans are primarily indirect clients for technologies, coupled with the fact that plans use varying bases of payment in paying providers, diffuses the strong cost containment incentives inherent in capitated managed care.

Medicare and Medicaid as Indirect Clients. Medicare and Medicaid are by far the two largest health insurance systems in the country. Hence, their coverage decisions and payment systems are extremely important to manufacturers. Although both public insurers were admittedly indirect clients, respondents placed far more emphasis on the payment policies of these payers versus private insurers care due to (a) their size, and (b) their bundled payment arrangements. This was true for Medicaid, even though it is 50 state programs rather than a single national program, in part, because of federal service coverage requirements.

Patients as Clients. Even though most health care is delivered directly to patients who must actively participate in their diagnosis and treatment, they are often forgotten as a client. This is because patients often defer to physicians regarding tests to be run and treatments to be undertaken. Yet, as services move to ambulatory settings, the patient is gaining as a direct client--particularly for drugs, as discussed in the next chapter.

Importance of Being the Direct Client. From respondents' comments on their clients, we note that device manufacturers bring products to market with several direct and indirect clients in mind, each with different perspectives on revenues, profits, the appropriate site of care, and the time horizon for savings. One is tempted to hypothesize the concept of a median client guiding marketing strategies, but all respondents would agree that they are not so sophisticated. They consider, first, who their direct clients are (largely hospitals and physicians), and then make some judgment as to which payment incentives dominate their clients' evaluation of a new or replacement technology. Indirect "clients," such as third-party payers, affect technology demand through this *ad hoc* weighting process. As we shall see, incentives embedded in some insurer payment systems may not be completely "passed on" to manufacturers.

6.5 Manufacturer Perceptions of Areas of Significant Managed Care Impact

Respondents noted three areas where managed care seemed to be having a noticeable impact. We discuss these observations below.

Managed Care Has Encouraged Shift to Ambulatory Care. No doubt exists among manufacturers on the critical role new technologies have played in shifting care out of the hospital. Endoscopic surgery, new drugs, and downsized screening equipment have enabled physicians to diagnose and treat patients on an outpatient basis. Managed care has also played a significant role in the site-of-care shift by avoiding admissions and shortening stays once a patient is admitted to a hospital.

Most manufacturers we interviewed believed their products were well suited to the new ambulatory care paradigm. Many are designing and manufacturing endoscopic devices. Others that produce more traditional diagnostic equipment, e.g., imagers, are enjoying increased demand from outpatient clinics set up to compete with hospitals. Hence, the decline in inpatient demand for many technologies has been offset to a considerable degree.

Entire new lines of business have also opened up responding to managed care's push for ambulatory care. Telemedicine is one of the most novel new areas. It also presents the greatest technological and payment challenges. Managed care plans, manufacturers recognize, are facing difficulty determining the ultimate value of home-based monitoring of health problems. Too much monitoring not only is costly, but inevitably raises the false positive rate (i.e., erroneous positive test results) leading to unnecessary and costly treatments.

It is nearly impossible to isolate the influences of technology and payment reforms such as managed care on the shift in the site of care, noted respondents. Undoubtedly, new technology provides the necessary condition behind much of the shift, e.g., arthroscopy, fast-acting narcotics. That is, without new surgical technologies and drugs, much of the shift to ambulatory diagnosis and treatment would not have been feasible. But managed care may have helped provide the sufficient condition that encouraged providers to make the change. Although the science existed to develop new medical devices to treat patients on an ambulatory basis (e.g., fiberoptics, miniature computer chips), without a change in financial incentives, physicians would likely have continued to treat most patients in the hospital. For the clinician, inpatient care is less hassled, more scheduled, often less risky, and affords better--and free—nursing and technician support.

Managed Care Has Adopted Bundled Payment Methodologies. Many managed care plans have adopted bundled payment for at least some providers. Bundled DRG or per diem payments are particularly common for hospitals. These bundled payments shift the financial risk of greater intensity and new device costs back onto providers, thus somewhat depressing the demand for new technology. In addition, they encourage the development of technologies that reduce the inputs to inpatient care. These include technologies that shorten length of stay, reduce stays in the ICU, shorten operating room times, and reduce the need for nursing and other costly labor inputs. Bundled payments have created pressures for manufacturers to demonstrate that their technologies can reduce the costs of care.

Managed care plans have adopted bundled payment methods from Medicare. Novel Medicare bundled payment methods such as DRGs and Ambulatory Patient Classes (APCs), discussed in more detail in section 6.10, are being borrowed as ready-made pricing tools to control utilization without incurring high utilization review costs. Plans can adopt Medicare bundled payment methods, noted one respondent, in large part because of the federal imprimatur certifying the rigor and scientific underpinnings of the methods.

Managed Care Encouraging More, and Different, Clinical Trials. One respondent felt that managed care did not have much effect on the company's R&D strategies, but that it was playing a role in the conduct of clinical trials. The uncertainty of the managed care coverage decision, coupled with lack of reimbursement during the experimental phase, is reported to be encouraging shorter, often simultaneous, trials. Because they are very expensive, manufacturers seek positive results from smaller, shorter trials. If encouraging results are obtained, innovators then approach health plans for funding of longer, more rigorous trials. Occasionally, manufacturers have been successful in gaining plan support for trials using plan facilities and patients. Smaller plans are uninterested in joint experimentation, according to the respondent, either because they are too small or lack their own facilities to conduct trials. There is also the free-rider problem, acknowledges the respondent. Smaller plans will adopt the new technology if it is found to be highly successful in trials funded in part by large plans.

6.6 Factors Limiting the Impact of Managed Care on Technology

In very few interviews was managed care mentioned as a major consideration in manufacturer R&D planning. Several different reasons were offered to explain this relatively minor emphasis.

Managed Care Unimportant in Many Localities. Marketers noted that the importance of managed care varies regionally. Penetration is very limited in the Rocky Mountain states, they reported. Managed care also is practically non-existent in rural areas, some respondents pointed out, and had entered smaller towns and cities in only a minor way. Even a few urbanized states, such as New York, had only recently dismantled their rate setting systems and opened up their provider markets to managed care.

Managed Care Coverage Not Directly Relevant to Many Technologies. Respondents stated that the importance of managed care varies by technology. Coverage was considered irrelevant by respondents for most technologies that had already become the norm of care, e.g., x-ray machines, patient monitors, beds, walkers, MRIs, and ultrasound equipment. Managed care only indirectly impacts the diffusion and replacement of these technologies, said manufacturers, through their payment policies, e.g., negotiated caps on hospital per diems. Reducing the purchase prices and operating costs of these technologies was emphasized, in part due to more stringent payments by managed care plans. Respondents agreed that managed care plans focus on very new, innovative, and costly technologies in making coverage decisions.

Managed Care Plans Engage in Favorable Patient Selection. One respondent explicitly mentioned the favorable selection strategy of many managed care plans. Defibrillators, just to cite one example, are not used as much by patients in many plans because relatively few subscribers have serious heart problems. Plans, the respondent maintained, were reluctant to provide ready access to new innovative technologies that may attract sicker members. Heightened premium competition among plans in recent years was predicted by respondents to further exacerbate favorable selection incentives. The net effect of managed care on manufacturer demand, therefore, was believed to be less than what the growth in managed care enrollment would indicate. This was because a disproportionate number of sicker patients remained under fee-for-service payment systems or enrolled in less stringent managed care plans.

Managed Care Plans Cannot Change Physician Practice Patterns. Even if a plan decides to cover a cost-effective device, respondents noted that it may not be able to convince physicians to use the cost-effective technology when appropriate. This was believed to be the case even for fairly centralized staff model managed care plans. Thus, even though plans may cover new technologies, they are not always able to lead their physicians away from older, less cost-effective technologies. Encouraging physicians to practice cost-effective medicine from the plan's perspective is challenging, device marketers admitted. Marketers noted that physicians are trained to do everything for the patient and any marginal gain in diagnostic accuracy or therapeutic efficacy is of value. Physicians do not see the need of avoiding downstream clinic visits from more costly diagnostic or therapeutic interventions in acute settings. Marketers felt physicians, whose financial success also depended on such visits, saw no economic advantage, either, to technologies that saved on physician services in the long run.

Many Forms of Managed Care Create Ambiguous Payment Signals. According to respondents, managed care came in many forms. Very few staff model managed care plans that own hospitals and tightly control equipment purchases still exist. The far more common arrangement is an Independent Practice Association (IPA) wherein managed care plans contract with many local providers. Managed care plans pay providers according to a variety of methods, including discounted fees, hospital per diems, hospital per case DRGs, primary care capitation, global surgical rates per procedure, global capitation, etc. The influence of managed care on provider adoption of new technologies depends upon how their contracts are structured, according to respondents. From our interviews, it was not clear how marketers addressed the mix of payment incentives to which providers are subject. One market manager said he did not even try. The firm made one reasoned argument for their products based largely on the cost savings to the hospital and contribution to patient outcomes.

One manufacturer reported that its sales force did consider the hospital's overall managed care population when making its sales arguments, noting that it was the basis of payment, more generally, and not the particular insurer, that molded the buyer's incentive structure. If half or two-thirds of a hospital's payments were under a bundled payment arrangement, e.g., DRGs or per diems, then inpatient technologies that reduced inpatient costs would naturally be more attractive.

Managed Care Payment Incentives Weak or Inconsistent for Physicians. Respondents recognized that almost all physician practices serve patients enrolled in a mix of indemnity and managed care insurance plans. Manufacturers believed that the majority of physicians, especially specialists who are involved in the purchase decision for most new technologies, continue to be paid on a fee-for-service basis, even by managed care plans. Medicare also continues to pay physicians primarily on a fee-for-service basis and only recently have state Medicaid programs began switching to capitation. Respondents concluded that because capitated patients form such a small part of most physician caseloads, providers naturally gravitate to the treatment style they learned in medical school. This style is usually compatible with the fee-for-service practice norms in the community. Manufacturers tended to discount physician complaints about plan denials and prior authorization, believing that physician behavior is still driven in large part by fee-for-service incentives to provide more services.

6.7 Role of Cost Effectiveness in Managed Care Coverage Decision Making

Respondents were asked to comment on how managed care plans use cost effectiveness analysis in making decisions regarding coverage and payment for new technologies. The effect that managed care has on manufacturer R&D strategies should be molded, in part, by how producers characterize plan decision making.

Managed Care Interest in Technology Cost Effectiveness was Uneven. Although managed care plans should have greater incentives than traditional indemnity insurers to consider cost effectiveness in their coverage decisions, the extent of their interest in rigorous cost effectiveness analyses of new devices is debatable, according to manufacturers. The newer the technology, however, the more emphasis is placed on cost effectiveness studies, respondents said.

One marketer noted a change in plan focus from financial analyses to patient outcomes and patient satisfaction. Originally, plans were mostly concerned about medical outlays and the organization's bottom line. Now, plans are emphasizing patient outcomes more as data become available and, according to the respondent, beneficiaries become more concerned about any plan limitations on access to care. One manufacturer reported that the firm abandoned a novel cardiac technology after conducting a sophisticated cost effectiveness analysis showing that the technology would just extend lives of questionable quality and, hence, would be difficult to justify to plans.

However, several respondents had a different characterization of plan emphasis on cost effectiveness analyses. A methodological strength of cost effectiveness analysis is that it takes into consideration downstream cost outlays and savings. Most manufacturers did not feel plans were sufficiently concerned about long-run cost savings. Although plans are still quite interested in avoiding hospital admissions, the idea of making up-front investments in new technologies and preventive care to avoid health problems five to ten years in the future is not taking hold.

Manufacturers believe that MCOs use cost effectiveness analyses mainly as a barrier to providing coverage. According to device marketers, managed care plans sometimes reject coverage of a device primarily by arguing that it is not efficacious or, even if efficacious, not cost effective. Plans will claim that the manufacturer does not have enough clinical trial publications in peer reviewed journals. If that hurdle is met, plans may argue that the manufacturer does not have enough articles in top tier journals to justify coverage, or that the publications are only by one researcher.

When managed care plans say they are concerned about the lack of efficacy of a particular technology, marketers almost uniformly interpreted this to mean that plans were very concerned about the cost implications of new devices. When plans question the device's value, according to manufacturers, cost seems to be paramount, rather than costs relative to effectiveness. Cost avoidance, marketers generally agreed, is of primary concern to plans who live in the short-run in a highly competitive environment.

Managed Care Plans Exaggerate Enrollee Turnover. According to an interviewee, plans sometimes exaggerate member turnover. The respondent felt that most plan managers truly believed that nearly everyone left his plan in six months. The perceived high turnover rate seemed to discourage plans from covering preventive care technologies or even those with longer-run benefits to patients. However, the person we interviewed believed the facts were quite different and that 20 percent turnover would be a high rate in a plan over several years.

Managed Care Plans Use Gatekeepers instead of Cost Effectiveness Guidelines. As noted above, respondents felt that plans did not enforce rigorous cost effectiveness guidelines often enough in making physicians practice appropriately. One respondent felt that some plans were less interested in cost effectiveness analysis because they used gatekeepers to limit access to expensive technologies directly. Gatekeepers were used in lieu of conducting and disseminating cost effectiveness analyses to physicians to influence their care patterns. Shifting financial responsibility for practicing efficiently onto physicians minimized plan efforts to conduct cost effectiveness analyses or make difficult coverage decisions. Manufacturers occasionally saw the gatekeeper approach as a drawback in their marketing efforts, in part, because the financial incentives facing physicians in the plan did not always encourage adoption of the most cost-effective technologies. Respondents did not believe that physicians loosely associated with a plan would bear all of the costs or receive all of the benefits that the plan would enjoy through the adoption of some of their products.

Managed Care Plans Propose Most Cost Effective Use First. Although manufacturers are skeptical about the role that rigorous cost effectiveness analysis plays in coverage decisions by managed care plans, they still feel that they must make a case based on cost effectiveness when marketing to plans. According to one respondent, when a manufacturer wants to get a new device covered by a plan, it is careful to put its best case forward first. This has caused some manufacturers to reject certain trials that do not put their product in the best possible light. The respondent emphasized that first impressions counted most with the plans. For example, a new diagnostic screening device may be best targeted to a limited high-risk group. The manufacturer's marketer would propose to plans that coverage be limited to select patient groups. In so doing, the firm can demonstrate superior cost effectiveness, while narrowing plans' financial risk from broad utilization of the device. Once the technology is covered and used, firms have found that physicians will see its value and extend its use to other patient groups. Meanwhile, the manufacturer can improve the technology, broaden its capabilities for other illnesses, and reduce its production costs, thereby raising overall cost effectiveness of the device for more patients.

6.8 Manufacturer Perceptions of the Future of Commercial Managed Care

The long-run impact of commercial managed care on R&D strategies and new technology innovation depends, in part, on predicted future growth in plan enrollment and the kinds of coverage and payment systems adopted.

Manufacturers Focus More on Current Managed Care Activity. When we asked all of the manufacturers how closely they tracked trends in managed care, most responded that they did not pay close attention to the market penetration numbers. Some marketing groups did have managed care penetration maps on their wall, suggesting they definitely paid attention to the spread of the phenomenon. Nevertheless, even in these firms, researchers did not statistically correlate managed care growth rates with sales across regions or over time. Respondents, they admitted, lived in the short run, paying close attention to the stock market and current corporate earnings reports. If plan coverage was critical to marketing a particular technology, e.g., PET scanners, telemedicine, implantables, firms paid close attention to current plan penetration and geographic concentration. It made no difference where managed care was going; it was here now for certain products.

Private Managed Care Believed to be Slowing Down. When we asked where they thought private managed care was going, marketers and R&D strategists said they had not given the question much thought. One marketer reported that national managed care penetration rates were slowing down and probably would not reach California levels. Respondents also believed that staff model managed care plans with stringent adoption and utilization guidelines for technologies would not become the predominant plan mode in the forseeable future.

Next, we probed for the reasons behind their impressions.

Managed Care Plans Not Suited for Small Markets. Respondents were aware that managed care was almost non-existent in rural areas. Even small urban areas were not experiencing much managed care growth, respondents noted. Two reasons were given. First, low population density areas are uneconomical to plans due to high enrollment and care management costs. Second, plans have difficulties negotiating favorable contracts with local hospitals and physicians who enjoy substantial market power due to their isolated markets.

Patient Dissatisfaction with Managed Care. Manufacturers are aware that many Americans are not happy with their managed care plan. A health services researcher at one company felt the pendulum has swung back from payers to physicians and patients. He doubted that the pendulum would swing back the other way as patients were speaking loud and clear. In the end, more than one respondent observed, technology "drives" managed care plans to broader coverage because it meets a basic need of patients. Patients and physicians are beginning to respond to attempts by managed care to restrict access to new technologies, manufacturers claim. Federal and state legislative initiatives support their claim.

The new Patients' Bill of Rights debate in states and Congress was cited as the logical outcome of patient and provider discontent. These bills restrict the ability of plans to deny access to new and established technologies. Guaranteed access to technologies is yet to be decided, but manufacturers are investing greater-and-greater R&D funds that society's decision will be favorable.

Managed Care Plans Cover Technologies for Competitive Reasons. One marketer reported, after having spent considerable time in the western United States, that provider-owned networks were upgrading their technologies to compete with larger managed care plans as full service local networks. Even large, closed panel managed care plans were having to offer point-of-service options for competitive reasons, noted the respondent. This limited the ability of previously more stringent plans to restrict access to high-technology services. Therefore, a more technology-friendly type of managed care plan was expected by the firm in the future.

6.9 Manufacturer Perceptions of Importance of Medicare Managed Care

No device manufacturer was concerned, specifically, over the introduction and growth of Medicare managed care. Several reasons were given to explain the lack of concern.

Medicare Utilization Minor for Some Technologies. A few manufacturers we interviewed had product lines oriented to the non-elderly--especially infants and children. These technologies involved screening and testing of infants and mothers, as well as special devices for addressing congenital birth defects. Other manufacturers had product lines focused more on the maternity population or workers in their middle years. While these products sometimes served an elderly population as well, the bulk of demand came from a much larger group of non-elderly patients. Unless the overwhelming majority of sales are to Medicare beneficiaries, marketers said they did not see a particular need to focus on Medicare managed care.

Medicare A Minor Part of Managed Care. One device marketer noted that Medicare managed care was only about 10 percent of the total managed care market. This was too small a percentage, he said, to justify a separate consideration of the public managed care initiative. Besides, recent trends appeared to be similar in both groups, according to respondents.

Medicare+Choice A Minor Part of the Medicare Program. Respondents also noted that the government's managed care initiative was still a small part of Medicare's overall program. Estimates of the size of Medicare+Choice by respondents ranged from 10 to 15 percent of all Medicare-eligible beneficiaries. They expressed skepticism that it would ever become the dominant part of Medicare. In addition, they predicted that the addition of an outpatient drug benefit to Medicare would reduce growth in enrollment because drug coverage is an important determinant of the decision to enroll in Medicare+Choice for many beneficiaries.

Medicare and Commercial Managed Care Quite Similar. Marketers we interviewed would also agree with one respondent's observation that public and commercial managed care were not materially different. Usually, Medicare managed care was implemented as another product line by commercial plans using similar management styles and coverage rules. Many Medicare plans, noted marketers, were IPAs with individual physicians treating both private and Medicare patients in a similar manner under similar, if not identical, incentives regarding the use of new technologies. It was not clear from our interviews how informed marketers were about differences between Medicare and commercial plans, such as Medicare's requirement to plow back excessive payments into greater benefits.

Medicare+Choice Payment Incentives Similar to Fee-for-Service Program. Respondents pointed out that the conversion of Medicare beneficiaries from fee-for-service to managed care had less of an impact on their market than with commercially insured patients. Whereas shifting commercially insured patients from a traditional indemnity plan to managed care could change hospital reimbursement from FFS to some form of bundled payment, this is not the case for Medicare beneficiaries because FFS Medicare already pays hospitals on a bundled per case basis. As noted previously, respondents emphasized more the basis of payment used by insurers to pay providers than whether patients, themselves, were enrolled in managed care.

Although the shift from FFS Medicare to managed care does not change hospital incentives to provide access to technology once a patient is admitted, managed care could potentially constrain the size of budgets available to invest in technology if hospital revenues decline due to reductions in admission rates. When queried about incentives Medicare+Choice plans have to avoid inpatient stays, respondents agreed this would effectively shift device demand to the ambulatory sector. However, one respondent also noted that Medicare Professional Review Organizations (PROs) have eliminated many unnecessary Medicare admissions since the PPS system was implemented. Therefore, Medicare+Choice plans may succeed in making only minor reductions in beneficiary inpatient admission rates—especially after controlling for less severe patient risk factors observed among Medicare+Choice enrollees (discussed below).

Medicare Managed Care Plans Favorably Select Patients. One health services researcher we interviewed stated that Medicare plans must carefully select enrollees to survive. Because the elderly are far more likely to use expensive health services, the financial risk of adverse selection of sicker patients is greater, he noted. Finally, a natural selection process was alleged to take place. The sick elderly and the disabled, those with chronic arthritis, heart failure, chronic obstructed lungs, or neurological impairments, generally remain in fee-for-service Medicare where no access constraints exist and where they can continue seeing the same physicians. The net effect of favorable selection bias, according to researchers at the device firms, was to weaken any negative demand trends accompanying the growth in Medicare managed care.

Medicare Beneficiaries Have Fee-for-Service Option. Respondents noted that the elderly had more options in choosing health insurance than private workers. Many private workers may be offered only one managed care plan by employers and no fee-for-service option. Respondents also emphasized the fact that workers are locked-in to a plan at least for a year. While employees may be able to choose a plan with a point-of-service option or other special coverages, these options usually required extra out-of-pocket co-premiums and copayments.

In contrast, the elderly and disabled who qualify for Medicare automatically receive fee-for-service health insurance coverage, which manufacturers consider quite generous. Manufacturers saw the Medicare fee-for-service option as a strong competitor to Medicare+Choice that forced plans to extend coverage to new technologies or otherwise offer additional benefits. Historically, at least, beneficiaries were also free to leave plans during the year, again unlike most private workers. This put further pressure on Medicare plans to compete in terms of coverage with Medicare fee-for-service, noted marketers.

Medicare Plans Biased Against Some Preventive Services. Whether Medicare managed care has a strong interest in preventive services was a debatable question among manufacturers. It was the general feeling among respondents that managed care organizations heavily discounted future savings for a variety of reasons; e.g., uncertain savings, high patient turnover rates, pressures on plan managers for short-run profits. One marketer had heard from some plans she talked to that the elderly had a relatively short lifespan and that any long-run savings from avoiding complications of one illness would likely go unrealized because of the onset of other debilitating illnesses. We also heard the counter-argument that Medicare plans are more inclined to cover preventive devices in order to avoid nearly certain, extraordinarily high costs later in life.

In talking with respondents we were able to reconcile the two viewpoints by whether or not the plan was aware of the health status of patients. If a patient already had a condition such as heart failure or artery occlusion, then preventive devices such as defibrillators and telemonitors may be cost effective from the plan's perspective. Future heart care needs are guaranteed for these patients. If they can be avoided through up-front prevention, the investment may be worthwhile.

If, on the other hand, a patient is asymptomatic but possibly facing higher illness risk, then preventive screening or therapeutic intervention may not be particularly cost effective--especially for Medicare managed care plans. Our respondent pointed out that the elderly are far more likely than the non-elderly to incur a range of major, life-threatening illnesses (e.g., strokes, heart attacks, organ failure, Alzheimer's, pneumonia, cancers), all involving major treatment costs. The advantages to screening or intervening with an elderly patient at higher risk of a particular health problem are quickly diluted if the patient incurs another unanticipated, expensive, illness in the not-so-distant future.

6.10 Manufacturer Perceptions Regarding the Importance of Fee-for-Service Medicare

Despite being relatively unconcerned about changing trends and policies in Medicare managed care, device manufacturers universally acknowledged the importance of the Medicare fee-for-service program for their industry. One high level R&D director admitted that the company concentrated its R&D and marketing efforts on direct Medicare payment, by which he meant the bases of payment for specific services or inpatient stays. A health service researcher in another very high technology firm said the company was quite concerned about HCFA payment and coverage of new technologies. Two reasons were cited, initially, for the emphasis on Medicare fee-for-service payment systems.

Dominant Size of Fee-for-Service Medicare. Manufacturers noted that the elderly and disabled, through Medicare, account for a disproportionate amount of health spending in the U.S. each year. The program has a significant effect on the demand for new technologies treating such serious illnesses as congestive heart failure (CHF), which affects hundreds of thousands of Americans each year and is a major cause of death. Many illnesses such as CHF occur almost exclusively among the elderly.

Medicare Fee-for-Service a Uniform Program. Respondents also emphasized that, in contrast with commercial fee-for-service insurers and managed care plans, Medicare sets policies nationally. While the overall private market is larger, no single private insurer covers over 30 million lives; moreover, said respondents, Medicare beneficiaries demand three to four times the health care of the average younger American. Securing coverage of a new technology in the private market can be a slow, plan-by-plan process. Similarly, private insurers use many different reimbursement mechanisms. When the government makes a payment change or a coverage decision, however, the financial implications for manufacturers are immediate and national.

Medicare Bases of Payment and Manufacturer R&D and Marketing. One of the strongest points emphasized by respondents was the critical importance of Medicare's various fee-for-service bases of payment. How Medicare pays for services creates a *de facto* marketing and R&D "target," to use one respondent's term. As a general rule, the more targeted the payment to the technology, the better off is the manufacturer in terms of product demand because providers are assured of revenues if they use the technology. One R&D director characterized his mission as developing a "coding path" to cover the new technology. Every manufacturer we interviewed had teams working in differing capacities on the coding path. One branch, usually stationed in Washington, D.C., was responsible for tracking new HCFA policies and rules that might influence reimbursement. A second marketing group interacted with providers, listening to their payment problems, suggesting alternative payment paths for their technologies, and taking back what they learned to the design engineers. Yet a third group of health services researchers conducted clinical trials and cost effectiveness analyses in order to convince providers of the long-run benefits of the device, and assist the Washington branch in justifying an alternative coding path to HCFA, if necessary.[5]

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[5] One example of industry success in modifying a coding path is in stent technology, a new device inserted in arteries to keep them open after angioplasty. HCFA agreed with the device industry that stents substantially raised the cost of angioplasty and in 1999 allowed hospitals to bill cases with stents under the higher priced DRG 116 rather than DRG 112--even though angioplasty with stents had nothing in common with other procedures in DRG 116. Yet another industry group was able to convince HCFA to reassign the implantation of a cardiac defibrillator to another, better paying, DRG. In this regard, the respondent we talked to believed that HCFA staff had an implicit $6,000 to $7,000 threshold in average total per case costs in order to acquiesce to a shift of a device to another DRG.

Firms construct a coding path, according to respondents, by building a coalition of nurses, physicians, and other device and drug manufacturers who become convinced of the medical value of a new technology. These groups assist in conducting clinical trials and cost effectiveness analyses, in ascertaining patient satisfaction, in suggesting refinements to the technology, and, finally, in lobbying insurers for coverage.

Medicare uses several different bases of payment today: per case DRGs for hospitals; highly fractionated CPT codes for physicians; per diems for nursing homes; and, now, per visit/procedure Ambulatory Procedure Classes (APCs). Each has somewhat different incentives for adopting new technologies depending upon the extent of service bundling and focus on specific technology.

The government's implementation of per case DRG hospital payment was certainly the most dramatic change to bases of payment since the passage of Medicare and Medicaid. Under earlier cost-based Medicare reimbursement, no direct link existed between services rendered to individual beneficiaries and payment to providers. Hospitals were paid retrospectively on costs incurred with no "benchmarking" against the costs of other providers. Once HCFA implemented hospital per case payment, DRGs became a clear target for manufacturers.

DRGs had two effects. First, paying on a per discharge basis shifted risk for more intensive, high technology care from Medicare to hospitals. Performing more MRIs or laboratory tests, for example, did not increase payment as it would have under cost-based payment. Hospitals naturally shifted that risk back to manufacturers to some extent by paying lower prices for technology, purchasing fewer devices, reducing inventories, etc. Respondents said they were left with two options. Either develop an argument why a new technology was more profitable to hospitals under an existing DRG or try to get the DRG modified in some way.

The second effect of DRGs was to identify patients in a particular way through the use of diagnostic groups, e.g., pneumonia, CHF, heart bypass. This focused manufacturers on developing technologies to treat patients with certain conditions or undergoing specific procedures. According to some respondents, this encouraged greater efficiencies in the diagnosis and treatment of particular illnesses. For others, DRGs encouraged newer, more efficacious devices that might require the creation of whole new DRGs. When they introduce a new technology, manufacturers reported that they first looked for a similar, or substitute, technology that is covered; e.g., bypass for angioplasty, pacemaker for implantable defibrillator. Then an argument is made that the new technology is (a) better, safer, and more convenient and/or (b) less costly on an inpatient basis. If a persuasive case can be made, HCFA may establish a new DRG and modify existing DRGs to "unbundle" the technology.[6]

Physician CPT codes provide an even more technology-specific basis of payment than inpatient DRGs. This is because they are so specific regarding both the technology and how the physician uses the technology for diagnosis and treatment. Manufacturers said they paid particular attention to the financial incentives embedded in these codes for physicians, in large part because physicians decide when to use the new technologies. If physicians are not paid for their effort through a CPT billing code, they are less enthusiastic about adopting a new technology. Thus, for Medicare fee-for-service, manufacturers say they must develop "coding paths" for both hospitals and physicians.[7]

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[6] One recent example involves bypass surgery and percutaneous transluminal angioplasty (PTCA). Since the inception of the DRG system, bypasses have been covered under DRGs 106, 107, and 108. PTCA was covered under DRG 112. Increasingly open angioplasty is being performed, however, in conjunction with bypass surgery. In the 1999 DRG grouper, the industry was successful in reserving DRG 106 for bypass with PTCA, shifting the other two bypass codes (with versus without cardiac catheterization) to DRGs 107 and 109. The effect is to raise the payment level to hospitals when surgeons perform open angioplasty.

Occasionally, CPT bases of payment that do not provide financial incentives for physicians to adopt a technology stymie engineering improvements made by manufacturers. One example that was cited involved an implantable defibrillator designed with two, rather than three, transvenous leads. Because these improvements in the leads resulted in a decline in physician work RVUs for the relevant CPT code, there reportedly was a corresponding decline in physician payment. Reduced payment was believed to have discouraged physician adoption of the simpler device.

The newest payment system is Medicare APCs for ambulatory services provided in outpatient departments and surgicenters, among other institutional locations. Analogous to inpatient DRGs, APCs group patients by a few hundred procedure and visit categories with a fixed payment per APC. Unlike DRGs, though, a single patient contact can involve two or more APCs with a combined payment. Minor tests are bundled into the fixed payment. The impact of Medicare managed care was viewed by respondents as quite secondary to the implications of the government's new bundled payment system. Given the large shift in care to ambulatory sites, the idea of bundling device (and drug) care into a single (or small number of) APCs, rather than reimbursing costs or paying discounted fees, has manufacturers working to develop new justifications for their technologies. As formerly with DRGs, our respondents say they have to make an argument why the hospital should incur the cost of a new prosthesis, catheter, drug, or the like when they will not receive additional Medicare payment.

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[7] One respondent felt that HCFA was reticent to cover Magnetic Resonance Angiography (MRA) and PET scans because they were relatively easy to perform on an outpatient basis and HCFA did not have a way of controlling unnecessary utilization. HCFA effectively restricted coverage, this person believed, by not having billable physician CPT vascular codes specifically for the procedures. Recently, PET demand has doubled, according to the respondent, with the new CPT billing codes for oncologists. In fact, clinicians interested in providing and billing Medicare for PET services allegedly were one of the most persuasive groups lobbying for coverage.

One device firm believed that it had been successful working with HCFA staff on the design of APCs even before they were implemented. The issue was the introduction and reimbursement of new technologies. Although in its initial regulation HCFA staff did not agree to establish a "new device" APC, they did agree to keep track of new technologies with the intent of eventually paying reasonable costs, possibly under a "new technology APC." After our interviews were completed, HCFA did respond to industry concerns by developing several "new technology" APC groups that range in payment from $50 to $6,000. [8]

CPT Codes as the Causeway of Technology Diffusion. Respondents recognized that physician specialists were the crucial decision makers behind the adoption of new technologies and the upgrading of existing devices. Interviewees implicitly categorized technologies into two groups: those that responded to existing physician billing codes, and those that created whole new codes. Technologies, they believed, fostered new codes, but once billing codes are established for the technologies, feedback effects from innovative applications of the technology fostered yet greater demand. This, respondents noted, often produced a proliferation of other CPT billing codes, thereby widening the reimbursement "causeway." PET scanning and implantables are just two of hundreds of examples of technologies that preceded billing codes.

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[8] Federal Register, Friday, April 7, 2000, p. 18477.

How HCFA and other payers manage the DRG and CPT/HCPCS classification systems is critical to manufacturers, we believe, both in their direct, immediate impact on demand and in their indirect feedback effect on future demand. Bundled payments, e.g., fee-for-service DRGs and now APCs, break the clear, sharp link between a new technology and targeted payment to hospitals adopting the technology. Capitation, an even more aggregate form of bundled payment, has the same effect on the provider receiving the capitation payment. The financial cost of technology utilization is borne by providers under bundled bases of payment. However, physicians mainly continue to receive payment on a per procedure basis. As long as payers maintain and routinely expand CPT coding for new technologies, the causeway permitting new technologies to feedback into increased health spending is secure. Bundled hospital payment may slow down physician adoption, but it will not stop it entirely.

6.11 Summary

Managed care has had a significant impact on the direction of R&D in the device industry in two key areas. First, reductions in inpatient utilization have encouraged a shift in R&D dollars to ambulatory-based technologies. The greater emphasis on ambulatory care has opened up new lines of business to device manufacturers (e.g., telemedicine) and has substantially expanded the number of potential clients. The device industry, constrained in the past primarily to acute hospitals, increasingly serves physician groups and other outpatient suppliers working in many environments, such as surgicenters, diagnostic clinics, and home health. Second, bundled provider payments, particularly for inpatient care, encourage development of technologies that reduce production costs. Manufacturers are under pressure to demonstrate that their products can reduce inputs to care, for example, by cutting length of stay or reducing labor inputs.

Nonetheless, in many respects, device manufacturers viewed the impact of managed care on R&D to be somewhat limited. On the most basic level, managed care does not alter many of the key forces that manufacturers cited as drivers of technological innovation. These include: (1) demographics, particularly the aging of the baby boom generation; (2) the growing importance of world markets; and (3) scientific advances that facilitate breakthrough discoveries. Manufacturers felt assured of strong demand for their new products, regardless of any changes in public policy, delivery system, or provider reimbursement methods.

Furthermore, managed care plans generally are not direct purchasers of devices and mainly influence their adoption indirectly through coverage decisions and payment policies.

For hospitals and physicians, who continue to be the key purchasers of devices, the basis of payment they receive is more important than managed care per se. However, managed care plans reimburse providers using a number of different payment mechanisms, with potentially conflicting incentives to adopt technology. Moreover, providers typically contract with many payers, only some of which are managed care plans. Specialists, who remain central to technology adoption decisions, still mainly receive FFS reimbursement under managed care and continue to maximize their revenues by adopting new technologies. Given that managed care sends providers signals that are substantially diffused, manufacturers find it difficult to factor these incentives into their decision making process. Instead, they focus primarily on FFS Medicare as the dominant payer in the health care system and on advancing technology to its limits.

Moving Medicare beneficiaries from FFS to managed care potentially could have a significant impact on R&D in the device industry given the sheer size of the program and the substantial health care needs of the elderly and disabled populations it covers. However, our interviewees cited a number of reasons why they did not consider growth in Medicare+Choice to be an important factor in developing their R&D agendas. First, Medicare managed care is not distinguishable from commercial managed care and does not require a unique response. Second, Medicare+Choice is a small portion of the Medicare program and they were skeptical that it would grow substantially in the future. Third, moving Medicare patients from FFS to managed care does not fundamentally change hospital incentives to adopt new technology because they already receive bundled payments under PPS. Indeed, to the extent that

Medicare+Choice plans reimburse hospitals using payment methods, such as discounted fees and per diems, that are less bundled than DRGs, the shift to Medicare managed care might even lessen hospital incentives to invest in cost-reducing technologies and avoid those that increase costs. Finally, favorable selection into Medicare+Choice plans leaves beneficiaries with the greatest demand for technology in the FFS system.

7

Case Studies of Pharmaceutical Manufacturers

7.1 Introduction

This chapter continues the synthesis of findings from interviews with pharmaceutical manufacturers. Managed care's relationship with the pharmaceutical industry differs from that with the device industry in several important ways. First, MCOs more often are direct purchasers of pharmaceuticals, whereas hospitals and physicians remain the direct client for most devices. Through the process of setting formularies, MCOs set coverage policies for most drugs that come on the market. Second, managed care plans have viewed drugs as a cost effective outpatient treatment alternative to inpatient care. Moreover, Medicare managed care is particularly advantageous because many Medicare+Choice plans offer outpatient drug coverage, whereas FFS Medicare does not. Thus, managed care growth has the potential to expand the market for pharmaceuticals, both by encouraging outpatient use and by broadening coverage beyond that which is offered in FFS Medicare.

This chapter reports the findings from our interviews with pharmaceutical manufacturers. Essentially the same interview protocol was used for both device and drug manufacturers. Many of the questions addressed in this chapter are similar to those in the previous one concerning the device industry. There was a fair degree of commonality in the perceptions of interviewees from the device and drug industries on certain issues. As a result, this chapter more briefly summarizes drug industry responses to issues that were discussed previously in Chapter 6 and focuses more deeply on those that are unique to pharmaceuticals. Questions addressed in this chapter include the following:

- What are the underlying factors influencing drug demand?
- What problems do manufacturers have with the purchasers of new drugs?
- How do manufacturers formulate their R&D strategies?
- What are manufacturer perceptions of managed care?
- What are manufacturer perceptions of Medicare managed care?

The remainder of the chapter is organized as follows. Section 7.2 discusses the major factors underlying the demand for pharmaceuticals as seen by manufacturers. Section 7.3 discusses problems manufacturers have with the coverage and payment policies of direct and indirect purchasers of drugs. Emphasis is given to flawed designs insurers use in conducting cost effectiveness analyses and setting their formularies. Section 7.4 outlines how firms mold their R&D strategies in response to managed care and patient needs. Respondent perceptions of the effects of managed care on their market are reviewed in Section 7.5. The section also discusses respondent perceptions of the future growth in managed care. Section 7.6 extends the previous section by summarizing perceptions of the impacts and expected future of Medicare managed care. The section concludes with respondents' explanation of why public policy initiatives to expand and constrain drug coverage over the last three decades have had little effect on the industry's fundamental R&D investment strategies, which are driven primarily by the aging population and emerging science.

7.2 Major Underlying Factors Influencing Demand for Drugs

Despite concerns about Food and Drug Administration (FDA) regulations that lengthened approval times and added to development costs, drug analysts were optimistic about the future demand for their products. Funding for drug R&D had risen rapidly in the industry, they reported, and company stock prices were high--two indications that the future looked good.

Favorable Demographics. A principal reason for the optimism was favorable U.S. demographics, particularly the aging of the population. Middle-aged workers today are predicted by respondents to have high expectations regarding the length and pleasure of their retirement years. With longer lives come more encounters with illnesses such as cancer, heart failure, strokes, and renal failure that can be treated through new drugs.

Respondents viewed the aging of the U.S. population as providing a “guaranteed” growing market over the next quarter century or more. When over 20 percent of the U.S. population is over 65 in a few decades, the absolute number of elderly will be twice what it is now. Thirty million new, well-insured elderly implies a substantial increase in medical need and market demand. Drug company forecasters reasoned that government support will grow even stronger for the medical needs of such a dominant voting block.

Shift to Ambulatory Care. Companies forecast that rapid growth in ambulatory sites of care will continue well into the future. As long as hospitals and other institutional settings are so expensive and take up such a large share of the health care dollar, health insurers will expand coverage of drugs that avoid or shorten inpatient stays.

Strong Growth in the World Market. Manufacturers reportedly are pursuing the world market very actively and have been for many years. As described in Chapter 6, their enthusiasm is based mostly on the relatively larger size of the world population. Although the United States constitutes a much larger share of the current world market for drugs because of citizens' wealth and health insurance, even limited growth in world-wide demand has a major influence on drug R&D spending and firm revenues because of the market's potential size.

A growing feedback, hinted at by interviewees, to the globalization of the drug market is worth noting. Currently, the U.S. exports new medical technologies (and any inflationary effects they might have) to the rest of the world. Increasingly, the world market is providing the resources to expand drug R&D development. The creation of new, innovative products, partially supported by international markets, may increase domestic health outlays, depending on the extent to which new drugs can avoid other costly medical interventions. Naturally, new drugs that save lives and improve the quality of life may well be worth the rising share of Gross Domestic Product.

7.3 Manufacturer Problems with Direct and Indirect Purchasers of New Drugs

Different Cost Effectiveness Perspectives. As with device technologies, pharmaceuticals are purchased, or covered, by a set of direct and indirect clients, including physicians, hospitals, insurers, and patients. Each group was seen has having a different perspective when evaluating the cost and effectiveness of their drug purchases. Physicians as producers of health services generally pay nothing for drugs. While this might result in too many prescriptions being recommended, manufacturers were also concerned that physicians have a bias against drugs that might reduce ambulatory visits to the provider. Hospitals purchase drug inventories for physicians, but are believed to consider only the purchase costs and immediate inpatient gains and not post-discharge cost savings. Finally, while insurers should consider the longer run outlays they might avoid through drug purchases, respondents felt their analyses generally had a fairly short-run perspective and did not take into account the long-run savings that might be achieved with certain drug therapies. Drug industry frustration with the limited perspective of purchaser evaluations of drug cost effectiveness was increasing recently with the adverse press about rapidly rising drug prices. An accurate cost effectiveness analysis should not only take into account the purchase price and immediate patient benefits in terms of improved health, but should also reflect any downstream cost savings or cost avoidance. Limitations on drug coverage and denials, it was believed, resulted from incomplete assessments of the true cost effectiveness of pharmaceuticals.

Formularies. The role of managed care plans as direct purchasers of pharmaceuticals distinguishes the nature of their impacts on the drug and device industries. MCOs direct drug purchases by setting formularies based on very detailed therapeutic classes that engender head-to-head competition between producers of drugs that accomplish the same medical function, e.g., anesthesia narcotics, anti-arthritics. No such classification system is employed by insurers in deciding which device technologies will be covered.

Insurers may decide not to cover an MRI exam for a particular patient, but they do not exclude certain MRI manufacturers from a list of acceptable MRI machines. While there may be a high level of competition in the device industry, it is not an outcome of MCO coverage decisions. In contrast, managed care directly fosters competition in the pharmaceutical industry by setting drug formularies that recognize the therapeutic equivalence of different manufacturers' products. Depending on the nature of the formulary, they may deny coverage entirely of products for which there is a lower-priced substitute or may require higher patient copayments for higher-priced products. Even plans with open formularies, which do not place special restrictions on non-formulary drugs, hope to guide providers toward prescribing their preferred products.

One weakness of the formularies noted by respondents was how insurers evaluate therapeutically similar drugs. Insurers and Pharmacy Benefit Managers (PBMs) were alleged to focus on narrow groups of therapeutic substitutes and simply seek the lowest bid. These assessments do not take into account related diagnosis and treatment costs, which actually might differ depending upon the product. Manufacturers argued that therapeutic substitutes are not necessarily equally cost effective and may differ in terms of patient compliance, outcomes, and complications, as well as the requirements for other medical resources to treat the case.

7.4 Drug Company R&D Strategies

Fewer "Me Too" Drugs. According to industry experts, formularies can be divided into four competitive classes. Class 1 includes the unique "blockbuster" drugs with no therapeutic substitutes. These constitute the billion dollar winners. Class 2 drugs include those in markets with two or more excellent branded drugs. Being second or third in this "crowded branded market" usually greatly diminishes profitability. Class 3 drugs include both brand-names and generics. Brand-name drugs are losers in this class, according to one respondent, even with patent extension. Class 4 includes only generic equivalent entities with minimal profitability and extreme cost consciousness in production.

Increasingly, the reported strategy of drug companies is to "demolish" a class by coming up with major new therapeutic enhancements, to use one respondent's description. He meant that some "blockbuster" drugs can quickly dominate a class of drugs, leaving very small market shares for other, increasingly obsolete brands. In some cases, this involves establishing an entirely new efficacy level, such as AZT for AIDS. However, a much quicker working antibiotic or faster acting anesthesia narcotic that shortens recuperation time in the ICU can also replace a whole set of previous entities. Fewer "me-too" drugs that offer minor improvements over competitors will be brought to market in the future, assured one pharmaceutical company researcher. Truly innovative drugs, the respondent noted, result in an increase in price and volume, making them double winners for manufacturers, while creating material gains in health for patients.

Developing the Target Product Profile for Marketing. Drug strategists and marketers report developing what they term a Target Product Profile that first determines the drug's *clinical efficacy*, then its *safety* (in terms of side effects, etc.), and finally its *economic value*. As with devices, tension exists between the scientists in the lab and the marketers trying to get their drugs on a formulary. One R&D director emphasized that the company must instill in the R&D scientists the need to focus on patient needs and not strictly the science. This is truer today than in the past.

As an example, he cited the fact that the company (and the industry as a whole) had ignored problems of cholesterol and occluded arteries for years, even though millions of Americans suffered from the problem and hundreds of thousands died from related heart problems each year. Once the industry started paying more attention to population vital statistics and future markets, a flood of hypertension and cholesterol-reducing drugs were introduced. He believed that the patient was directing the science more today than a decade ago. A health services research physician in another company agreed, commenting that manufacturers are looking for truly unmet need.

More Cost Effectiveness Analyses. Both analysts emphasized that the question of economic value to purchasers is entering into the company's R&D decision process far earlier and more forcefully than previously. Knowing producers will eventually have to convince insurers of the economic value of their new product, respondents maintained that cost effectiveness analyses are started much earlier in the drug's development phase.

Certain difficulties arise from early studies, however, before drug testing is completed. Unfortunately, lack of rigorous information on the cost of illness hampers efforts to estimate cost avoidance. Baseline use rates are often nonexistent or attainable only through expensive, time-consuming patient studies or claims processing. Moreover, the key long-run cost savings are highly speculative earlier on in the process. Patency rates are key to determining longer-run readmission rates for thrombolysis treatment of occluded arteries, for example, but are only known after the drug is perfected and widely used. Manufacturers are looking harder at long-run cost avoidance, nonetheless, given rising drug prices and buyer skepticism of touted long-run cost savings.

Minimizing the Attrition (Failure) Problem. According to one respondent, the biggest R&D problem has always been the high attrition, or failure, rate between initial development efforts in the laboratory and final marketing. He claimed that there are 12 products in discovery for every product that reaches the market. Therefore, the scientific challenge was to attack a problem with over 100,000 molecular possibilities. Because animal studies do not guarantee safety and efficacy in humans, companies are increasingly testing more drug combinations--first approved in the laboratory--on humans.

This implies two strategies: one quickly narrows the list of viable products to those deemed most promising, while a second actually widens the list to include less certain products. The appeal of a wider list of tested products appears to be predicated on the uncertainty over future side effects and efficacy for any single product. Many more "shots on goal" are being taken in order to "score one big hit," to use the respondent's own terms to describe the broadening of the product list. Although firms experience higher attrition in the human testing phase, developers and physicians obtain valuable feedback on unexpected side effects. The respondent maintained that this was the way Viagra was discovered--as a positive side effect. With more products being tested, the chances of discovering a "blockbuster drug" increases.

7.5 Drug Manufacturer Perceptions of Managed Care

Respondents had mixed impressions of the impact of managed care on the pharmaceutical industry. On the one hand, its great strength was its focus on treating the whole patient episode and not just the inpatient stay. On the other hand, respondents felt plans still did not take a broad, societal perspective in making their coverage and pricing decisions.

Treating the Whole Episode. To the extent MCOs are financially responsible for the costs of an entire episode of care, reported one R&D director, they force providers (and physicians, in particular) to look holistically at patient care. This was viewed quite favorably as drugs can be very cost effective substitutes. For example, the respondent maintained that managed care plans are more receptive to drugs that treat depression, incontinence drugs that treat the whole episode, and drugs that aid cardiomyopathy treatments because these types of interventions could help keep patients out of the hospital and, in some cases, reduce the need for medical care in the future. Another respondent cited the strong demand of profit-oriented plans for his company's products, even at a higher price, as evidence of the cost effectiveness of drug interventions. They are willing to pay more for value, he asserted, because plan managers are at risk for inpatient utilization and greater outlays if they do not take advantage of opportunities for aggressive case management using drugs on an ambulatory basis.

Another industry researcher was not so sanguine about the willingness of managed care plans to consider the whole patient episode. He felt that managed care plans tended to ignore product differences that might reduce patient risk or enhance comfort. Plans often demanded long-run studies demonstrating the drug's cost effectiveness, but would not pay for the data collection and analysis on their patients.

Plans were also alleged to undervalue the long-run contribution of chronic care drugs. Plan executives, he maintained, are focused on quarterly profits and discount future cost savings heavily. He believed plans were somewhat adverse to extending drug coverage without demonstrable short run cost savings on other medical services. In part, his argument was based on the relatively short management tenure of senior plan executives. The respondent also believed that plan managers tend to treat drugs strictly as an investment with an expected financial return to the plan (and stockholders), rather than fully considering patients' benefits from a better quality of life.

Emphasis on Truly Innovative Drugs. Respondents gave considerable credit to the spread of managed care as a driver behind the shift away from "me-too" drugs to more innovative "blockbuster" drugs that provide major treatment advances. Although MCOs are more willing than hospitals and physicians operating under fee-for-service arrangements to substitute drugs for other forms of health care, they also expect these drugs to lead to substantial improvements in health. This emphasis, in turn, reinforces the growing need (due to the higher prices they can command) to be "first in class." Our respondent believed that from the plan's perspective, "first in class" meant "only in class," with no coverage for substitutes that did not offer substantial advantages, either in terms of price or treatment efficacy.

Plan emphasis on covering only "first in class" drugs reportedly caused one pharmaceutical company to discontinue development of a drug that had a projected potential $100 million market and was expected to have positive health benefits because they believed managed care's limited formularies had made the market too narrow. We believe that the interviewee meant by this that the product in development was not innovative enough to gain a substantial share of the existing market served by lower priced drugs. The company did not think it could make a strong enough case relative to existing therapies with enough plans to widen the market any further.

Biases Against Genetic Engineering. One respondent reported that managed care plans are very concerned that biotechnology firms might develop new genetic tests with the capability to identify currently untreatable problems. Not only are these tests expensive individually, there are potentially many such tests for various risk factors. Even more of a concern to plans, said the respondent, is the implied obligation of the plan to cover any additional monitoring and treatment of the latent risk, however ineffective.

Higher Premium on Drug Compliance. Respondents further noted the greater emphasis of managed care plans on drug compliance by patients. Under fee-for-service, physicians are little concerned about patient non-compliance except for the adverse health impacts. Managed care plans, unlike physicians, incur the cost of additional treatment as a result of non-compliance. Consequently, drug marketers must assure plans that patients will be willing and able to complete their drug regimens. Cost effectiveness studies conducted by manufacturers must screen in advance for patient non-compliance and modify the form of delivery to maximize compliance (for example, by reducing the number of doses required). This is another area in which marketers are talking more with bench scientists on drug design.

Direct Patient Advertising and Information. Historically, drug companies queried physicians about new drugs and what they would like to see in the way of product development. Companies also engaged extensively in drug detailing with individual physicians to inform them of their product's therapeutic advantages. Manufacturers' access to physicians, respondents claimed, has been greatly restricted in recent years, partly by changes in Medicare bases of payment to inpatient per case DRGs that limited hospital formularies and partly to the spread of managed care. Both hospital and plan formularies are centrally determined. According to our respondent, this has forced companies to shift to direct patient advertising.

Companies are adopting a "pull through" (respondent's term) marketing strategy using a host of print, TV, and computer-based media. Drug firms are described by respondents as "pulling patients through" the restrictive guidelines adopted by managed care plans by talking to patients directly about their products. Respondents also claim that patients are becoming concerned that managed care physicians might be denying them the proper care. Direct to consumer advertising empowers patients to ask questions about specific drug alternatives. The Internet, in particular, provides low cost access to information for patients, who then become more proactive in managing their care.

Expected Future Growth in Managed Care. Several respondents believed that managed care had made impressive strides in reducing unnecessary utilization of health services--particularly inpatient care. They also credited plans with negotiating substantial price discounts over traditional fee-for-service medicine. Respondents asserted that managed care plans are now faced with much tougher case management decisions. Some, they said, likely will not meet the challenge and will disappear. One respondent believed that if managed care plans go much further in restricting access to care, patients would return to less restrictive insurance plans and support legislation limiting the ability of plans to deny care.

One respondent was optimistic that drugs would fare well if plans shifted their emphasis from price discounting to true case management. Drugs, he maintained, are the cornerstone of patient care management outside the hospital. Thus, he did not expect the perceived limits on the growth in managed care to have a material effect on industry growth. Either patients would remain in less restrictive plans or plans would begin to take even more advantage of pharmaceuticals to manage patient care more cost effectively.

7.6 Drug Manufacturer Perceptions of Medicare Managed Care

Medicare+Choice Expands Drug Demand. Respondents noted a primary difference in the impact of Medicare managed care on demand for pharmaceuticals as compared to devices. Medicare does not cover outpatient drugs, but does cover ambulatory utilization of most types of diagnostic and therapeutic equipment. Many Medicare+Choice plans have extended drug coverage as a competitive enticement to join the plan. Therefore, drug manufacturers we interviewed regard Medicare managed care as a positive influence on the demand for their products. Hence, Medicare managed care is not considered a particular problem for the industry because it expands, rather than contracts, overall demand.

Capping Medicare+Choice Drug Coverage. Although respondents viewed the provision of drug coverage to the elderly as one of the greatest strengths of Medicare managed care, one respondent noted that many plans are now capping coverage at $1,000 or $1,500 per year. Certain high penetration markets, such as Miami, are an exception to this trend, he said, because of the high concentration of elderly and active competition among plans for the large elderly market. Unlimited drug coverage continues to be used in Florida, he believed, as an enticement to enroll.

Caps on drug coverage, continued the respondent, will reinforce the elderly's generally greater interest in health care access. As plans limit drug access, the elderly will pay increasing attention to direct advertising and seek alternative substitutes for expensive drugs by using the Internet. Caps on drug benefits were believed to reinforce the broader restrictions on access by plans, thereby increasing direct marketing by drug manufacturers to patients.

Expected Future Growth in Medicare Managed Care. All respondents we interviewed felt that Medicare+Choice had a positive impact on the demand for their products. First, drugs play a key role in managing patients, especially elderly patients with multiple expensive illnesses. Second, many of the Medicare managed care plans have extended drug coverage to the elderly as a marketing strategy. However, they felt two factors might reduce the potential for further expansion in drug demand from Medicare+Choice.

The most direct factor is the lower payment caps on drug outlays being imposed by many plans. Respondents thought this trend would likely continue, first, to save money and, second, to avoid adverse selection of sicker elderly patients into plans.

The indirect factor is the increased federal interest in offering ambulatory drug coverage under fee-for-service Medicare. One respondent maintained that a portion of the Medicare+Choice population would eventually return to fee-for-service Medicare if it offered drug coverage. They would return to their previous physician, if excluded from the managed care plan, and would prefer the unconstrained fee-for-service program.

One respondent believed that the very act of Medicare managed care extending drug coverage to the elderly heightened expectations. Many patients who switched to Medicare+Choice in order to get access to costly drugs cannot return to Medicare fee-for-service without suffering severe financial hardship. Now that plans are reducing the drug benefit, the elderly who did join plans will be even more vocal supporters of the proposed drug expansion in the regular program.

We made several attempts to contact an expert at PhARMA, the industry association, on its general position regarding Medicare ambulatory drug coverage, but our calls were not returned. Based on the impressions of one manufacturer respondent, the industry now supports the idea of extending coverage under fee-for-service Medicare. He also believed that any coverage plan will involve some discounts or "rebates," similar to the Medicaid system. If a manufacturer offered a better price to a private purchaser, it would have to rebate some or all of the percentage difference between the Medicare and private price to the government. Our respondent believed that large volume increases over all Medicare beneficiaries could compensate for the rebates or price discounts. Other experts we interviewed doubted that volume gains could offset deep price discounts.

Impact of Uncertain Policy Changes on R&D Strategies. Respondents certainly emphasized the positive aspects of Medicare+Choice on the demand for their products. We next asked them what effect all of the actual and proposed changes in drug coverage in both FFS Medicare and Medicare+Choice had on their R&D strategies. One key respondent in charge of his company's R&D strategy reported that because of uncertainty about how these changes would play out in the long run, they had relatively little impact. The primary reason was the long time lag to bring a new drug to market. He stated that it took ten years, in general, from the time a molecular compound is discovered until the time it is in widespread use, if ever. He felt it was nearly impossible for his firm to develop predictive models of drug demand that far in the future based on previous Medicare (and Medicaid) experience. Medicare+Choice and Medicaid managed care have emerged only in the last decade. Commercial managed care, too, had only taken hold in a major way in the last 10 to 12 years. As a result, managed care was too recent a phenomenon to have had an observable impact on drugs in the pipeline. Given the protracted time frame for bringing new drugs to market and uncertainty about the long-run importance and direction of managed care, managed care did not have much weight in shaping this manufacturer's R&D strategy.

Policy changes that create unanticipated "shocks" to the system (e.g., providing drug coverage under Medicare) potentially have major effects on market demand. However, because these shocks cannot be anticipated, manufacturers are not able to factor them into their R&D strategies, which must look a decade or more into the future. As a result, manufacturers' R&D agendas are driven by more certain and powerful long-run forces, such as the aging of the population, as well as basic science and opportunities to take maximum advantage of advances in areas such as genetic engineering. While manufacturers report discarding minor innovations sooner and seeking better drugs to help manage the whole episode of care, so far the managed care initiative has not had reported dramatic effects on the level or direction of pharmaceutical R&D investment.

7.7 Summary

Unlike devices, where managed care plays only an indirect role in technology adoption decisions, MCOs more often are direct purchasers of pharmaceuticals. Through the process of setting formularies, managed care plans determine coverage policies for most drugs that come on the market, thereby magnifying the direct competition between products that are therapeutic substitutes. Formularies may deny coverage of some brands entirely or at least influence demand by setting differential copayment levels.

Pharmaceutical manufacturers have responded to formularies in several ways. First, they are far less likely to bring "me-too" drugs to market. Instead, they focus on discovery of innovative "blockbuster" drugs that can dominate a class of drugs either because of their uniqueness or their superiority to potential substitutes. Second, manufacturers recognize that they must be able to demonstrate the economic value of their products. As a result, cost effectiveness analyses enter the R&D decision making process earlier and play a more important role. Nonetheless, pharmaceutical manufacturers feel that MCOs are often more concerned about cost avoidance than true cost effectiveness and do not fully take into account long run cost savings. In addition, formulary decisions do not always recognize differences between therapeutic substitutes in terms of outcomes, side effects, compliance, and requirements for other medical resources to treat the case. Third, the use of centrally-determined formularies has restricted the ability of manufacturers to develop a market for their product through direct contact with physicians. As a result, they increasingly have adopted direct to consumer advertising strategies in order to generate patient demand.

Despite these impacts, the manufacturers interviewed did not feel that managed care would have a suppressive effect on innovation in the pharmaceutical industry. Like device manufacturers, they believed that demographic trends and growth in world markets assured strong future demand for their products. Growth opportunities in biotechnology also justified major new R&D investments by pharmaceutical manufacturers. In addition, drugs are a cornerstone of the ambulatory care treatment orientation of MCOs. Pharmaceutical manufacturers viewed Medicare managed care as having a particularly positive impact on demand for their products because, unlike FFS Medicare, many Medicare+Choice plans offer drug coverage. Nonetheless, Medicare managed care, and managed care generally, are fairly recent developments. Given the long time lags in bringing new drugs to market, manufacturers see too much uncertainty about managed care's long term prospects and direction to fundamentally alter their R&D strategies in response.

8

Implications for Research on Managed Care and Technology

8.1 Introduction

There is a considerable literature, both theoretical and empirical, that explores the nexus between managed care, technology adoption and innovation, and health care spending growth. Much of this literature was reviewed in Chapter 2. While broad models have been proposed, the debate on the nature of these relationships is far from closed. Moreover, a consistent story has not emerged from the empirical research conducted to date.

Any observed correlation between managed care, technology adoption and diffusion, and technology research and development undoubtedly reflects the combined effect of many, perhaps conflicting, forces. Our study sought to illuminate this complex set of relationships by going inside managed care organizations and device and drug manufacturers in order to better understand their respective decision making processes and the factors that drive them. The preceding four chapters of this report separately discussed the findings from our case studies of these two sides of the technology supply and demand equation. In this chapter, we synthesize the lessons learned from these sets of case studies, review them in relation to the current literature, and propose some directions for future research derived from our findings.

8.2 Synthesis of Case Study Findings

In this section, we identify nine key hypotheses drawn from the literature about the links between managed care and technology, in terms of both its development and adoption. Underlying interest in these relationships is the assumption that managed care can change the path of future health care spending growth by slowing or halting the adoption of costly new technologies and, in turn, by encouraging manufacturers to focus their research and development efforts on cost-effective, rather than cost-increasing, technologies. We review findings from our case studies, drawing together lessons learned from the MCO and manufacturer perspectives, in light of their implications for these nine hypotheses from the current literature.

Hypothesis #1: Managed care plans are less likely to cover costly new technologies and more likely to restrict access to them than fee-for-service plans.

It has been widely hypothesized that managed care plans are more likely deny coverage of costly new technologies than traditional fee-for-service insurers, although empirical evidence on the impact of managed care on technology adoption and diffusion is mixed. Viewed in its simplest form, our interviews with MCOs and manufacturers refute this hypothesis. This is not to say that managed care covers all technologies regardless of cost, but the effects are felt in more subtle ways and they operate within a limited range.

Managed care works at the cutting edge of new technologies in making coverage decisions. Plans only evaluate a small percentage of the new technologies that come on the market because the assessment process is very costly. Assessments are usually targeted at high cost or controversial technologies, although more coverage decisions are made for individual drugs through the process of setting the formulary. Coverage issues are moot for most technologies that have already become part of the norms of care. Manufacturers distinguish between innovative, "visible" technologies that require a new "coding path" to payment and those that either have an established path (say, via a DRG or CPT code) or are not directly billed under bundled payment (e.g., x-rays, lab tests). For thousands of established technologies, providers are the only clients, and managed care plays no role in adoption other than through broader payment incentives. Few individual managed care plans are large enough to directly influence provider purchase decisions. While some managed care plans are direct purchasers of technology because they own their own facilities, they are a diminishing share of the market.

Plans rarely have a blanket policy of refusing to cover a technology. When they do, they say it is usually because it is considered investigational or experimental and the safety and efficacy of the technology has not been demonstrated. Some managed care plans even relax this policy and have instituted limited coverage of experimental treatments provided through an approved clinical trial. All plans indicated that they would not refuse to cover a technology that had been generally accepted as the standard of care, no matter how expensive. Our interviewees at managed care plans stressed the clinical orientation of their technology assessment process and stated that cost is very rarely an explicit consideration.

Rather than having a blanket no-coverage policy, it is far more common for MCOs to cover a technology subject to medical necessity criteria. However, plans may find it difficult to limit use to only those conditions specified in their criteria. Indeed, manufacturers view gaining coverage for a limited group of patients as key. This provides an opportunity for physicians to familiarize themselves with the technology. Once the technology has proven itself to clinicians, pressures build for wider use for other illnesses and patient age groups. Plans certainly recognize how the indications for which a technology is used can expand once it is adopted, which is why coverage even on a limited basis can be so contentious. The evolution of managed care away from traditional staff and group model plans toward more loosely organized forms such as IPA-model plans makes it more difficult to enforce medical necessity policies. Given these constraints on their ability to directly control use, plans have attempted to off-load risk to providers using bundled payments. The most extreme form is full capitation, but the spread of this form of contracting is being limited by consumer and provider backlash.

Managed care plans also face substantial external pressures that make it difficult to limit coverage. There has been an explosion in patient demand for new technologies, particularly as the Internet and direct-to-consumer advertising arms them with information about treatment alternatives. Far from facing pressures to reduce costs, in the current economic boom plans are encouraged by employers and consumers to adopt less restrictive policies. Plans are also reluctant to alienate members of their provider panel. They are acutely aware of public distrust of their industry and are anxious to avoid the bad publicity generated by coverage denials, particularly for treatment of life-threatening conditions. Indeed, they may feel forced to conform fairly closely to fee-for-service practice norms in order to gain legitimacy with the public. Recent large liability judgments against managed care plans have only heightened their anxieties. In many states, plans face regulations that restrict their ability to deny coverage of certain services. Growing interest in Patients' Bill of Rights legislation further focuses these pressures.

Hypothesis #2: Medicare managed care reinforces commercial managed care in slowing the development and diffusion of new, cost-increasing medical technologies.

If commercial managed care is having any demonstrable impact on technology coverage and development, it is reasonable to expect the conversion of Medicare beneficiaries to managed care to be reinforcing. After all, Medicare is by far the largest single insurer of health care and covers two populations with substantial health care needs-the elderly and the disabled.

Yet, when manufacturer R&D directors and marketers were interviewed, they universally agreed that Medicare managed care was not an important consideration for them. They meant this in two ways, the first consistent with the general hypothesis. Respondents acknowledged that Medicare reinforces commercial managed care, but their effects were largely the same. Medicare managed care was implemented in ways very similar to commercial plans and the incentive structures were analogous.

But respondents also meant something else very important when they said Medicare managed care was of little concern. First, particularly for hospitals, incentives to adopt technologies are little changed by the shift from FFS Medicare to Medicare+Choice because they receive bundled payments under both systems. For example, bundled inpatient DRG payments already make hospitals quite cost conscious when purchasing new technologies. Indeed, to the extent that hospitals are able to negotiate less bundled payments with MCOs (e.g., per diems or evens FFS reimbursement), the move to Medicare managed care may diminish their incentives to reduce costs.

Second, although potentially quite devastating to the burgeoning demand for new technologies, respondents observed that Medicare managed care plans tend to enroll the healthiest beneficiaries, thereby leaving the demand for costly technologies relatively untouched in the fee-for-service sector. In addition, Medicare beneficiaries enrolled in Medicare+Choice plans would always be able to vote with their feet and return to fee-for-service if they felt that they had been denied access to new technologies.

Third, manufacturers did not expect that a significant percent of the elderly would ever join managed care plans. They believe that the addition of an outpatient drug benefit to fee-for-service Medicare would reduce enrollment growth since drug coverage is one of the strongest attractions of Medicare managed care. Fourth, coverage of outpatient drugs under many Medicare managed care plans, unlike current fee-for-service Medicare, actually was a positive influence for pharmaceutical demand and new product development.

Hypothesis #3: Managed care plans limit utilization by rationing quantities, while fee-for-service insurers rely on cost sharing.

Traditionally, managed care plans are assumed to limit service use by directly rationing quantities. Providers modulate access to services and set appropriate treatment levels within a category of illness. Staff and group model plans that own their facilities may also ration by limiting the availability of technologies through regionalization or long waiting times. Fee-for-service insurers, on the other hand, are assumed to use beneficiary cost sharing to limit patient demand. However, they do not directly constrain providers' treatment decisions. While there is certainly truth in these stylized facts, our case studies show that these distinctions between managed care and fee-for-service insurance are becoming increasingly blurred.

Virtually every plan interviewed established medical necessity criteria for the use of costly technologies and guidelines for the treatment of certain conditions. However, these practices are not restricted to managed care plans. Several of the plans interviewed also offered fee-for-service products and in every case coverage policies and treatment guidelines applied uniformly to all of their product lines. Given that plans view guidelines as promoting treatment safety and efficacy, not limiting costs, they saw no justification for not applying them to all product lines. Although these guidelines may be enforced more rigorously under managed care, the distinction is one of degree, not of kind.

Despite the widespread use of treatment guidelines, their power to constrain utilization is limited because it is difficult to monitor their enforcement. Medical necessity criteria, which may be based on complex diagnostic indications and treatment history, often cannot be incorporated in automated claims processing systems. Plans may find it difficult to control "off-label" use of technologies that have been approved for limited indications. While plans use prior authorization or utilization review for some technologies, these types of audit mechanisms are labor intensive and too expensive to use routinely. In addition, they are unpopular with providers, who view them as intrusive and onerous. Therefore, they are typically limited to selected low volume, high unit cost technologies. Because of the difficulties entailed in direct enforcement of guidelines, plans place considerable focus on provider education and use the guidelines as a means to disseminate information about the appropriate use of new technologies.

Although managed care plans traditionally did not require patient cost sharing at the point of service, given the limitations on the effectiveness of treatment guidelines for controlling utilization, they increasingly use copayments to increase beneficiary price sensitivity. Cost sharing is particularly widely used for prescription drugs, where plan costs have been escalating rapidly. In this area, plans are adopting differential copayment levels to direct prescribing patterns. While some plans have had differential copayments levels for formulary and non-formulary drugs, there is a growing move to a three-tier structure with the lowest level for generic drugs, an intermediate level for formulary brand-name drugs, and the highest level for non-formulary brand-name drugs. Plans are also considering extending cost sharing requirements to other areas, such as a copayment for an emergency room visit that does not result in an admission or a deductible for inpatient stays. Office visit copayments, which most plans have, may also be increased. While cost sharing is widely adopted as a utilization control measure in commercial plans, it is less applicable in public insurance programs, such as Medicaid where use of cost sharing is limited by legislative mandate and the low-income level of beneficiaries.

Hypothesis #4: Managed care plans engage in rigorous cost effectiveness studies of new technologies in their coverage decisions.

Unlike traditional fee-for-service payment systems, managed care plans might be expected to undertake rigorous cost effectiveness analysis of new technologies before covering them in order to control health care spending. If plans have embraced cost effectiveness analysis in their coverage decisions, this should rationalize technology adoption and slow the development and diffusion of costly technologies of marginal value.

Managed care plans, however, admitted that they rarely use cost effectiveness analysis in their coverage decisions. Either the necessary data is not available or it is simply too expensive for individual plans, or even the technology assessment organizations they consult with, to undertake. As a result, coverage decisions are based on meta-analysis of the literature that focus on the efficacy of the technology, its net effect on patient outcomes, improvement over existing technologies, and the likelihood of continued superiority in a non-investigational setting.

Manufacturer respondents paint a different picture. Marketers to plans are usually asked to justify coverage of new technologies by providing rigorous published information on cost effectiveness. Debate surrounds the meaning of "effectiveness." Manufacturers like to interpret effectiveness as "value," which to them means long-run savings and better outcomes justifying a higher price. Plan decision-makers, manufacturers claim, use effectiveness to mean "cost avoidance." Will adopting the new technology save the plan money with no harm to the patient?

Although managed care plans have greater incentives than traditional FFS insurers to take cost effectiveness into account in their coverage decisions, there remains a fundamental mismatch between the time horizon under which plans operate and the long-run perspective of cost effectiveness analysis. Evaluation of the cost effectiveness of a new technology should theoretically take into account the full stream of costs and benefits over time, with those occurring in the future subject to some discount rate. However, MCOs have no guarantee that a given member will remain enrolled in their plan in the long-run. As a result, they heavily discount the value of improved outcomes or costs avoided more than a few years in the future, if they consider them at all. Furthermore, managed care plans naturally focus on direct health care costs and benefits, rather than the full range of social costs and benefits. For example, their evaluations are unlikely to consider the value of new technology in terms of increased workplace productivity through reductions in time lost from work or improved performance. Though better suited to considering cost effectiveness in their coverage decisions than FFS insurers, MCOs operate under incentives that make them far from the perfect venue for assessing the value of new technologies, at least from a societal perspective.

Hypothesis #5: Medical care manufacturers mold their R&D spending to changes in insurer methods of payment and managed care.

In evaluating this hypothesis it is key to distinguish two kinds of payment changes--ones that reduce the net cost to patients at point-of-use and others that alter the way providers are paid. It is universally recognized that the spread of insurance coverage since the mid-1960s has lowered the net cost of care to patients, providing access to care that they otherwise could not afford. This has encouraged manufacturers to invest heavily in R&D to bring new health care products to market, recognizing that insurers are very likely to cover most, if not all, of the price. It is this feedback effect of R&D spending on future patient demand that is believed to be driving the continued shift of resources into the health sector.

Policy makers have been concerned for over 25 years that the rate of increase in health care spending is too high. They have enacted many changes in payment policies designed to correct the highly inflationary cost-based reimbursement methods prevalent in the post-Medicare/Medicaid period (i.e., after 1965). Medicare PPS is undoubtedly the most significant payment change faced by medical care manufacturers in the past 25 years. Managed care, the major response in the private and Medicaid sectors, creates incentives that in many respects reinforce those under Medicare PPS.

Despite these fundamental payment changes, the rate of growth in health spending has far exceeded the rate of domestic production and prices generally in the economy. However, this does not mean that new, presumably less inflationary, payment methods have had no material impact on manufacturer R&D spending. Our case studies of device and drug manufacturers indicate that new payment methods have had profound effects, but more in the types of technologies being developed than in the level of new investment and subsequent technical advances. As to types of products developed, we found that radical payment changes such as Medicare inpatient DRGs and capitated managed care have molded manufacturer R&D in three very different ways.

Bundled payment. Widespread use of bundled payments (including DRGs, per diems, and capitation) encourages providers, especially hospitals, to seek ways to reduce the costs of care. Emphasis is almost exclusively on lowering hospital inpatient inputs to care, e.g., shorter stays and less nursing, shorter ICU and operating room times. Manufacturers are under growing pressure to demonstrate that new equipment models save costs by shortening times or reducing costly labor inputs. DRGs, in particular, provide targets for manufacturers. Engineers and chemists have been put to work getting cost out of the care for inpatients with an identified illness or undergoing a particular procedure.

Shift in site of care. By encouraging shorter stays or by denying unnecessary admissions, these payment changes have fostered enormous growth in ambulatory surgery and other forms of outpatient care. Tremendous growth in the ambulatory care infrastructure has opened up large markets for new technologies, e.g., telemedicine, outpatient drug management, imaging clinics, home health. Innovative R&D spending is being channeled to ambulatory care technologies, broadening the market further and addressing quality of life issues well beyond the acute inpatient episode. Although hospital spending has slowed dramatically in the last 15 years, whether this shift will be cost reducing or cost increasing in the long-run is unknown. However, net spending decreases from shifts in the site of care may be far less than imagined. First, patients have much better access to costly technologies that previously required hospitalization and, consequently, are more inclined to use them. Outpatient endoscopic surgery is a prime example. Telemedicine, spawned by the new, managed care ideology, is reaching out to populations heretofore almost entirely ignored by the institutional health sector. Second, physicians, in particular, have become more entrepreneurial in directly providing costly services on an outpatient basis. This, in turn, has greatly expanded the number of potential customers for new technologies beyond 5,000 acute care hospitals.

Blockbuster Technologies. Managed care's use of cost effectiveness criteria and bundled payment has forced manufacturers to shift R&D investment to blockbuster devices and drugs. From the manufacturer perspective, "being first in class may mean being the only one in class." This is especially true for new drugs. Manufacturers report leaving some entities "on the table" rather than bringing them to market to compete with several other therapeutic substitutes. Instead, they look for products with potential for "demolishing the whole class of drugs." To the extent manufacturers are successful in developing truly innovative products, medical care costs could rise rather than fall. Of course, patients should benefit greatly from successful products; yet, the net effect may well be a rising share of GDP devoted to medical care.

Hypothesis #6: Managed care restricts the diffusion of new technologies by molding the adoption decisions of providers.

Managed care can exert a potent impact on the diffusion of new technologies by influencing the likelihood that providers will adopt them. Although manufacturers still have physicians and hospitals as their primary customers, for several reasons, managed care plans are seen more-and-more as "virtual clients" through their coverage decisions, utilization management activities, and provider payment policies.

For providers, the basis of payment is more important than the delivery system per se. Hospitals clearly understand the incentives created by DRGs or per diem payments. While they are concerned about the payment method, in this respect managed care plans are viewed no differently from other payers, especially Medicare. With the exception of hospitals and physicians operating within closed systems, such as Kaiser, providers typically contract with many insurers, only some of which are managed care plans. Their technology adoption decisions must somehow integrate the incentives of these multiple payers. Device marketers said they took into consideration the scope of bundled payment contracts when talking with a hospital's physicians and purchasing departments. It made little difference whether payments were capitated or based on per case DRGs; the incentives to "take cost out of inpatient production" were the same.

Given the multiplicity of incentives facing providers, managed care will not have an important effect on provider adoption decisions unless it reaches a certain threshold level. Providers appear to be most sensitive to payers with dominant market shares. In many of our conversations with hospitals, for example, they spoke of Medicare fee-for-service coverage and payment policies as the most influential. Indeed, outside of extremely highly penetrated markets where managed care is the predominant delivery system, such as Los Angeles, managed care did not appear to have a substantial influence on hospital adoption decisions. Managed care has a limited impact on academic medical centers, where the drive to remain at the forefront of technology is predominant. As a result, these hospitals remain a conduit for new technologies that then diffuse to the general medical community.

The spread of managed care, with its emphasis on prospective per diem and per case payments, has limited hospitals' ability to shift higher device and drug costs to private payers. However, most of the hospitals we interviewed were not facing serious financial constraints attributed to managed care. Either managed care was a minor share of their patient base, or they were able to negotiate favorable contracts because of their competitive position, or they were operating with high occupancy rates. However, hospitals in markets with high levels of managed care penetration and community hospitals were more likely to feel the pinch. Nonetheless, greater use of bundled payments by all payers has encouraged hospitals to adopt technologies that reduce production and operating costs.

Marketing to physicians was deemed by manufacturers to be key to selling new technologies. Indeed, our interviews with hospitals indicate that the predominant place of physicians in the technology adoption decision is unchanged. Although staff model HMOs generally isolated physicians from marketing initiatives of manufacturers, these plans are a declining share of the managed care market. More loosely organized forms of managed care, such as IPAs, have no mechanism to limit producer access to providers. Manufacturers view the billing impacts on physicians as key to their ability to market technologies. Fee-for-service physician payment by MCOs and Medicare offset the negative demand effects of bundled hospital payment systems. Because most specialists are still paid discounted fee-for-service by public and private insurers, manufacturers consider physician behavior to be "still driven by fee-for-service." However, physicians will be considerably less enthusiastic about adopting a new technology if there is no CPT code they can use to bill for it. Thus, a crucial part of manufacturers' marketing strategies is identifying the "coding path" to reimbursement for their technology.

Hypothesis #7: Both managed care plans and providers use new technologies to compete for subscribers and patients, which, in turn, supports new technology development among manufacturers.

In our interviews, we found that plans wanted to have a general reputation for providing access to good quality care, but did not want to be seen as the market leader for treating specific high cost chronic illnesses. Plans wanted to be seen as offering good quality care to be a credible competitor for the business of employers, or to attract individual Medicare enrollees. Good quality care includes access to medical technologies, including expensive, life-saving technologies. Plans seem to use their provider network to signal the availability of complex, tertiary care services. In several markets where we interviewed, plans regarded it as essential to include a tertiary-care, academic medical center in their provider network. Plans did not want to acquire a reputation, publicized through the mass media, of denying access to life-saving technologies. They might consider giving access to such services even against their best judgment to avoid acquiring a negative reputation for denying care.

On the other hand, plans try to avoid adverse selection when designing their provider networks, benefit packages, and technology offerings. They do not market their leadership in treating expensive chronic conditions such as HIV/AIDS, congestive heart failure, or cancer. Nor do they specifically promote the availability of expensive treatments such as bone marrow transplants in their plan. In theory, risk adjustment should mitigate some of the disincentive to cultivate a reputation for excellence in treating high cost illnesses.

Providers may or may not use technology as a competitive advantage, depending on how they are paid. We interviewed at a hospital in Chicago that heavily promoted its 'gamma knife' brain surgery technology. This expensive technology is not widespread, is in demand by patients, and is reimbursed by many insurers. It is profitable for the hospital as a line of business. Another nearby hospital is acquiring the same technology to compete. Indeed, hospitals do not find that the availability of technology makes them unattractive to managed care plans and may, in fact, feel that they need to offer certain technologies in order to compete for contracts. On the other hand, many physician groups in the Los Angeles market are capitated for a large portion of their revenues. They face the same possibility of adverse selection as health plans and, therefore, try to avoid attracting a chronically ill population. One, for example, dismantled a disease management program for congestive heart failure, while another indicated that they do not contract with top-tier hospitals.

Hypothesis #8: Access to costly technologies is more restricted in markets where there is greater competition between managed care plans.

It is has been hypothesized that in the past managed care has not had a substantial impact on technology adoption because of its limited market penetration. Given that fee-for-service insurance remained the dominant form in most areas, managed care plans could gain market share by setting their premiums just below those of fee-for-service insurers. "Shadow pricing" enabled managed care plans to compete by simply discounting payment rates or reducing hospitalization rates. However, as enrollment in managed care grows, plans will compete head to head and will be forced to adopt more fundamental changes in service delivery patterns. As a result, we expected that plans in high penetration market areas would have more restrictive coverage policies for high cost technologies. While there was some truth to this, particularly in Los Angeles, we found less variation in coverage policies across market areas than we anticipated. A number of factors, in fact, led to a good deal of uniformity across markets.

First, many managed care plans in local markets are affiliates of national plans. All of the national plans interviewed set their coverage policies centrally. Any variation across markets is a reflection of local legislative mandates. Much of the impetus for this centralization comes from large national employers and unions, who want to provide consistent benefits across the country. Although local affiliates apply these policies to specific cases and they may not be interpreted uniformly at the local level, respondents at the headquarters of national plans did not feel this was a serious problem. In addition, local affiliates did not feel that having to apply standardized, national policies to their local markets placed them at a competitive disadvantage, particularly since they contend that their guidelines are based on scientific evidence that is invariant to market conditions.

Second, plans are relying on many of the same sources for information to set their policies. There are a handful of organizations conducting technology assessments to which nearly all plans subscribe. Their coverage policies generally closely follow the recommendations of these technology assessment organizations. Indeed, one of the advantages to using these externally conducted assessments is that it insulates a plan from local provider pressures.

Finally, evidence of small area practice pattern variation aside, plans believe that their coverage policies reflect generally accepted treatment norms. Although there may be some friction when a technology is first introduced, plans feel that they usually arrive at the same coverage policies as a consensus about the appropriate use of a new technology emerges over time within the medical community.

Hypothesis #9: Population growth, the aging of the population, and higher incomes explain only a small portion of the growth in health spending and, by extension, R&D spending on new technologies.

Actuarial and statistical studies of trends in U.S. health spending show that population demographics and income status play only a minor role, contributing only 10 to 15 percent annually to the growth rate. Research has found a larger role for rapid declines in patient out-of-pocket prices for care. Moreover, after controlling for demographics and price trends, the large unexplained residual component of growth is ascribed to "the march of science" and new technologies. Three factors confound a simple interpretation of the historical facts and make future predictions unreliable based on past correlations.

First, regardless of any other changes in the health care system, both device and drug manufacturers claimed that future U.S. population demographics justified continued growth in their R&D spending and bringing new products to market. Baby boomers were expected to accelerate demand as they begin to retire 10 years from now. The first 30 years post-Medicare/Medicaid inception was dominated by the spread of insurance coverage; however, population demographics were not changing appreciably during most of this period. Health demand in the next 30 years, manufacturers believe, will be increasingly dominated by the aging of the population, which will replace insurance as the driving factor.

Second, historically, growth in manufacturer demand has been driven by the U.S. market. In the last couple of decades, the world market has opened up to device and drug manufacturers. As a result, R&D spending will be less and less sensitive to changes in domestic payment policies. Now, even if the U.S. market slowed for some reason, worldwide demand for devices and drugs will likely increase, manufacturers believe. This has potentially large spillover effects on U.S. health care spending via strong R&D spending on new technologies.

Third, scientific advances germane to medical care are stronger than ever. Computer miniaturization, fiberoptics, magnets, imaging, transtelephonic communication, and other technologies developed elsewhere in the economy are transforming medical diagnosis and treatment. Genetic engineering, manufacturers believe, may be an even more powerful driver of future health demand. As current science begins to peak in a particular area, biotechnology will more than fill the gap with new, impossible to ignore, products. Managed care plans are "terrified" over the coming genetic revolution that could identify untreatable diseases and isolate high risk patients at great costs of screening the entire population. The aging population and wealthier citizens in general will find ways to pay for many of these new technologies, so manufacturers believe. Venture capital firms appear to agree with biotechnology firm predictions, thereby closing the link between projected future demand and R&D spending on technologies necessary to "bring the new demand to market."

8.3 Directions for Future Research

Our study used the decision making processes of MCOs and health care manufacturers as a lens for understanding how managed care might alter the feedback relationship between insurance, technology, and health care spending growth. While our study provided insights into the complex factors that influence MCO and manufacturer decisions, we are only able to speculate about outcomes with respect to technology adoption, diffusion, and innovation, much less expenditure growth. Nonetheless, our findings suggest some reasons why the current literature on this set of relationships is inconclusive. There are many possible avenues for future research in this area. Here, we suggest eight directions derived from our study findings.

Utilization Controls vs. Cost Sharing. Our case studies indicate fundamental limits on the capacity of utilization controls to restrict the use of technology. Although MCOs try to establish treatment protocols, evaluating technology and monitoring compliance with medical necessity criteria are costly undertakings. As a result, plans are increasingly turning to patient cost-sharing as a cost control tool. However, there are many unanswered questions about use of these alternative mechanisms. We speculate that it may be difficult for MCOs to enforce treatment guidelines, but is this in fact the case? Do closed and open-panel managed care models differ in their ability to enforce protocols? Which is more effective at limiting technology use--treatment protocols or cost sharing? Are there particular technologies for which one is more effective than the other? Are there differences between organizational forms of managed care in the relative effectiveness of these tools?

Organizational Form of Managed Care. It is well-recognized that managed care is an evolving organizational form. Traditional closed-panel models like Kaiser are no longer the norm and more loosely organized IPA-model plans are on the rise. Indeed, PPOs and POS plans blur the line between managed care and indemnity insurance, as does the adoption of utilization management tools by traditional insurance plans. Treating managed care as a monolithic entity when considering technology coverage misses the important distinctions between plans. Are some forms of managed care more effective than others at controlling use of technology? What are the key organizational features that influence differences in the ability to control technology--e.g., provider organization (closed or open panel), provider payment policies (FFS, bundled unit payments, capitation), ownership of facilities, profit status, national affiliation, age, size? Are different forms of managed care more effective at controlling some types of technologies than others?

Spillover Effects from Managed Care. It has been hypothesized that there may by significant spillover effects from managed care to the FFS sector. Our study suggests that technology assessment is one area in which this spillover has occurred. Although our sample was limited, every one of our interview sites that offered both FFS and managed care options applied the same coverage policies across product lines. Does this finding hold up in a larger sample? Do FFS insurers that do not offer managed care products also adopt coverage policies? If so, how do they differ from those of insurers with managed care products? Are managed care plans better able to enforce coverage policies than FFS? Do practice norms generally differ by the level of managed care penetration?

Coverage Denials by MCOs. There is a widespread public perception that managed care plans significantly restrict access to services through their coverage denials. Is this the case or are there a relatively small number of highly publicized cases? A physician survey showed that managed care plans rarely deny coverage of routine care (e.g., hospitalizations, surgical procedures, specialist referrals, diagnostic tests) and that most denials were reversed on appeal (Remler, 1997). Do these findings hold for emerging technologies? Do managed care plans deny coverage of cutting edge technologies that are covered by FFS plans? Does the likelihood of a denial vary by the type of plan or maturity of the managed care market?

Short-run vs. Long-run Effects. One of the primary ways that managed care reduces health care spending is by reducing volume (particularly of inpatient services) and by negotiating discounted prices. These are changes that can be made fairly quickly, whereas fundamental changes in practice norms and infrastructure via its impact on technology adoption would be felt in the long-run. While studies have looked at spending growth in high vs. low penetration markets, there has been less research in patterns of spending growth over time. How does spending growth in a market that has had a long history of high managed care penetration compare with one that has recently undergone rapid growth? How does spending growth in long-established high penetration markets compare in early growth years vs. later years?

Relative Spending Growth by Sector. Important technological innovation is disproportionately located in a few sectors of the health care market. Technology adoption is expected to be far more important in hospitals than in nursing homes, for example. How does spending growth in technology-intensive sectors compare with that in sectors that rely less on technology? Has relative growth changed over time? Has the path of spending growth changed in sectors heavily influenced by managed care (e.g., hospital and ambulatory care) relative to those that are comparatively untouched (e.g., home health and SNF)?

Direct vs. Indirect Impacts of Managed Care on Technology Growth. Managed care can influence the use of technology, both directly through their coverage policies and indirectly through the effect of volume and payment changes on providers. Our study looked only cursorily at provider adoption decisions, although our findings suggest that payment changes are more important than coverage policies per se. Does this finding hold up in a more in-depth study of providers? Are there differences by market area? Is there a threshold level of managed care penetration (at the market and hospital level) before managed care has an effect? Do the effects of managed care and the path by which these effects are felt differ in community hospitals compared to teaching hospitals?

Impact of Payment Changes on R&D Portfolio. Our interviews suggest that managed care, along with other payment changes, has contributed to a shift in the mix of manufacturer R&D portfolios. Among the changes described are greater emphasis on ambulatory technologies, technologies that reduce production costs, and blockbuster technologies. Are these changes observed in the products coming to market now? Are they observed in products in the pipeline?

8.4 Conclusion

Managed care plans influence the adoption and use of new technologies, through both their coverage policies and their use of bundled provider payments. This, in turn, has influenced manufacturer R&D strategies in several ways. First, they have responded to reduced utilization of inpatient services by shifting R&D dollars to ambulatory care. Second, particularly in pharmaceuticals, MCOs have created price competition among substituting technologies which has spawned a growing emphasis on discovery of "blockbuster" technologies. Third, manufacturers increasingly feel they must be able to argue for the cost effectiveness of their technologies, although they contend that MCOs are interested more in short-run cost avoidance and plans concede that they rarely incorporate cost effectiveness analysis in their coverage decisions. Fourth, bundled provider payments, particularly for inpatient care, encourage development of technologies that reduce production costs. However, on a fundamental level, managed care has no impact on several of the key forces driving technological innovation: (1) demographics, particularly the aging of the baby boom generation; (2) the growing importance of world markets; and (3) scientific advances that facilitate breakthrough discoveries.

It is also not clear that the changes engendered by managed care necessarily alter the feedback relationship between technology and health care spending growth. Although blockbuster technologies undoubtedly bring substantial benefits to patients, spending may increase because they broaden the definition of health care and command high prices. While ambulatory care may be a more cost-effective mode of delivery, the shift to this new site of care has required a substantial investment in new infrastructure and has increased demand for treatments that previously might have been foregone because they required hospitalization.

The ability of managed care to restrict the diffusion of technologies that do come to market is constrained in many respects. Despite their adoption of coverage guidelines, plans may not be able to enforce them rigorously. Covering a technology for limited indications provides a toehold that later can become the basis for broader coverage. Physicians and hospitals are the primary market for most technologies and MCOs only exert an indirect influence on them. These providers still face powerful incentives to adopt new technologies that are little changed under managed care. Finally, managed care plans face powerful external pressures-from patients, purchasers, politicians, and the media-that make it difficult for them to deny coverage of services. As a result, MCOs are turning to strategies, such as greater patient cost sharing, that are more associated with traditional indemnity insurance.

It is important to recognize that our study was conducted under a particular set of economic conditions that may have exerted a significant impact on our findings. In many markets, insurers have kept premium increases low (perhaps artificially so) for several years. In the present robust economy, employers use generous benefits to compete in a tight labor market. As a result, managed care plans are being pressured to adopt less, not more, restrictive coverage policies. In the end, patient willingness to pay, whether through greater cost sharing or higher insurance premiums, will determine the rate of technology diffusion. Currently, it appears that the will to pay remains strong. However, these findings could certainly change with a return to double-digit premium increases or an economic downturn.

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Appendix 1

Participant List

Appendix 1

Participant List

Managed Care Organizations

- Accord Health Plan (Chicago)
- Blue Shield of California
- BlueCross BlueShield of Massachusetts
- CIGNA HealthCare (national headquarters)
- CIGNA HealthCare of California
- CIGNA HealthCare of Texas
- Fallon Health Plan (Worcester, Massachusetts)
- First Choice Health Plan (Seattle)
- Group Health Cooperative of Puget Sound (Seattle)
- Harvard Pilgrim Health Plan (Boston)
- Kaiser Permanente (national headquarters)
- Kaiser Permanente (Southern California)
- Memorial Sisters of Charity (Houston)
- Methodist Care (Houston)
- PacifiCare (national headquarters)
- PacifiCare of California
- PacifiCare of Texas
- Providence Health Plans (Portland)
- Prudential Health Plan (national headquarters)
- Regence BlueCross BlueShield of Oregon
- Tufts Health Care Plan (Boston)
- United HealthCare (national headquarters)
- United HealthCare (Chicago)

Hospitals

- Brigham and Women's Hospital (Boston)
- Catholic Health Partners (Chicago)
- Harborview Medical Center (Seattle)
- Memorial - Hermann Health System (Houston)
- Methodist Health Care System (Houston)
- St. Luke's Episcopal Hospital (Houston)
- Swedish Medical Center (Seattle)
- UCLA Medical Center
- University of Chicago Hospital

Physician Groups

- Bristol Park Medical Group (Southern California)
- HealthCare Partners Ltd. (Southern California)
- Partners Community Health Care (Boston)
- Virginia Mason (Seattle)

Device Manufacturers

- Boston Scientific
- GE Medical Systems
- Hewlett-Packard
- Medtronic

Pharmaceutical Manufacturers

- Genzyme Genetics
- Smith/Kline Beecham Pharmaceuticals
- Pfizer, Inc.

Other

- BlueCross BlueShield Technology Evaluation Center
- Center for Health Dispute Resolution
- Health Industry Manufacturers Association
- Medical Alley Associates
- Medical Care Ombudsman Program
- Prescription Solutions

Appendix 2

Interview Protocols

Appendix 2

Interview Protocols

MCO Protocol

Information Gathered Prior to On-Site Interview.

- Model type, profit status, national affiliation.
- Age of MCO, years in this market, years in Medicare.
- Number of MCOs in the market.
- Managed care penetration rate in the market: overall, commercial, Medicare, Medicaid.
- Describe how physicians affiliated with the plan are organized.

  Probe: To what degree is there centralized control over providers?
- Describe the reimbursement methods used for: primary care physicians, specialists, hospitals, and ancillary services (pharmacy, laboratory, radiology).

  Probe: Does the plan have global capitation or percentage of premium contracts with any physician groups?

  Probe: Have your reimbursement methods changed recently? Are changes anticipated in the future?
- What is the distribution of the plan's enrolled population: employed, Medicare, Medicaid, other.
- Who are the important players in the market?

  Probe: Is there a dominant MCO, dominant hospital, dominant employer, business coalition?
- Did your plan earn a profit in the past five years?

- How much have premiums changed in the past five years (commercial, Medicare)?

Market Characteristics.

- Would you describe this market as competitive?

  Probe: Is managed care an important force in this market?

- Do you expect the competitiveness of the market to change in the next five years?

  Probe: Changes in managed care penetration, number of plans, profitability, premium levels?

When Does the MCO Make Technology Coverage Decisions?

- Under what circumstances does the MCO make a coverage decision versus case-by-case determination of medical necessity?

  Probe: For what types of technologies are they likely to make coverage decisions?

  Probe: How does the MCO identify technologies on which coverage decisions will be made?

  Probe: What prompts the plan to make a coverage decision?

- What is the role of the national affiliate in making coverage decisions and medical necessity decisions?

  Probe: If the national affiliate plays a central role, how does it convey and enforce these decisions at the local plan level?

  Probe: Does centralization of coverage decisions affect their ability to compete in the local market?

- Do technology coverage policies differ across MCO offerings?

  Probe: Between Medicare and commercial products?

Probe: If the company also offers indemnity products, are coverage policies different from those in MCO offerings?

Probe: Are differences across products enforced?

How Does the MCO Make Technology Coverage Decisions?

- Using the example of [Viagra, Cox 2 inhibitors, Ceredase, Clariton, ABC drugs for multiple schlerosis, PET scans, lung volume reduction surgery, bone marrow transplantation for solid tumor breast cancer, thin prep pap tests, proton beam therapy], describe the procedures used to make technology coverage decisions for [pharmaceuticals, medical devices, surgical procedures].

  Probe: What is the MCO's coverage policy?

  Probe: What are the coverage policies of the MCO's two main competitors in the market?

  Probe: Who was involved in making the decision?

  Probe: What types of information were used to make the decision (cost-effectiveness, efficacy, marketing)?

  Probe: What considerations influenced this policy (medical necessity, economic, safety, liability, market competition, FDA approval)?

  Probe: What is required to move a technology from experimental status to accepted practice?

  Probe: Was this typical of the decision making process used for [pharmaceuticals, medical devices, surgical procedures]? If not, how did it differ?

  Probe: Would the coverage policy change if managed care penetration increased by 50 percent?

- Describe the procedures used to make medical necessity decisions.

- Have the procedures used to make coverage decisions changed over time? Are they expected to change in the future?

- Is there an up-and-coming technology on which the MCO expects to make a coverage decision in the near future? What will be the basis for this decision?

- How do the following influence coverage decisions: physicians associated with the MCO, competitors' policies, large employers, business groups, consumer demand, the availability of a technology at a contracting hospital, coverage policies of Medicare and local Medicare carrier?

- Do coverage decisions have an impact on the MCO's market share?

  Probe: Medicare market? Commercial market?

  Probe: How is this impact assessed?

  Probe: Is the coverage of specific technologies used to market the MCO?

How Does the MCO Control Utilization of Technology?

- What mechanisms does the MCO use to control diffusion of technologies that are covered?

  Probe: Protocols or formularies, prior authorization, network design, payment methodology, utilization review, profiling?

- Is there a mechanism for re-assessing and, if appropriate, "de-listing" older technologies that have been superceded by a newly-covered technology?

- Are there mechanisms that allow beneficiaries to bypass coverage policies?

  Probe: Is there an exception process to bypass coverage policies? Is it used often?

  Probe: Does the plan have provisions to assist members in gaining access to ongoing clinical trials? Does the plan participate in clinical trials?

  Probe: Have beneficiaries made use of Medicare policies regarding complaints and grievances to gain access to uncovered technologies?

- How does the availability of expensive technologies or expertise affect contractual relationships with hospitals?

Additional Drug Coverage Issues.

- What is the MCO's policy regarding use of generic drugs?

- Does the MCO contract with a pharmacy benefits manager (PBM)? How was it chosen? How was the quality of the products offered by different PBMs assessed?

Decision-making Related to Plan Offerings.

- Describe the MCO's range of plan offerings in terms of benefits, premiums, and copayments: Medicare, commercial.

  Probe: What are the basic benefits included in all offerings?

  Probe: How do Medicare offerings compare with their most generous commercial plans?

  Probe: What additional benefits beyond standard Medicare benefits does the MCO offer Medicare beneficiaries?

  Probe: Which of these are always included in Medicare offerings?

  Probe: How does the MCO's current range of offerings compare to those five years ago?

  Probe: How are offerings expected to change over the next five years?

  Probe: How would a 50 percent increase in managed care penetration affect the MCO's plan offerings?

- How does the plan make decisions about plan offerings: Medicare, commercial?

  Probe: How does the plan make decisions about the trade-off between premium, copayment, and benefit levels?

  Probe: How are plan offerings influenced by the national affiliate, other MCOs in the market, the indemnity market, employers?

- How are recent changes in Medicare's methods for setting capitation payments expected to change payments rates in this market area? Will this have an effect on benefit offerings? On coverage decisions?
- Are any other Medicare policy changes expected to affect offerings or coverage decisions?

Hospital Protocol

Information Gathered Prior to On-Site Interview.

- Number of hospitals in the market area.
- Hospital closures and mergers in market area.
- Market share and occupancy rate of hospitals in market area.

Market Characteristics.

- Would you describe the hospital market as competitive?

  Probe: Number of hospitals, competition for patients, competition for MCO contracts.

  Probe: Is this expected to change over the next five years?

  Probe: Are any hospital closures or mergers expected?

- How is the hospital's market share and occupancy rate expected to change over the next five years?
  Probe: How does this compare to other hospitals in the market area?

Relationships with MCOs.

- How important is managed care to the hospital?

  Probe: What percent of their overall patient base is represented by managed care?

Probe: What percent of their Medicare admissions are for people enrolled in managed care?

Probe: Are managed care enrollees an increasing, decreasing, or constant share of the hospital's patient base?

Probe: Is this expected to change in the next five years?

- With which MCOs does the hospital contract?

  Probe: Is the hospital selective in choosing MCOs to contract with?

  Probe: Which MCO is their major source of revenues?

  Probe: Is there an MCO in which they are the dominant hospital?

- What reimbursement arrangements do they have with MCOs?

  Probe: Have your reimbursement arrangements changed recently? Are changes anticipated in the future?

Processes for Making Technology Adoption Decisions.

- How does the hospital identify technologies on which adoption decisions will be made: surgical procedures, devices, drugs?

- What is the role of the hospital administration versus physicians in making technology adoption decisions?

  Probe: How do they interact?

  Probe: Has managed care altered the relation between physicians and the hospital in technology decision making?

- Describe a recent decision to adopt and not adopt a technology in each of the following areas: pharmaceuticals, radiology, laboratory, surgical procedure, equipment.

  Probe: Who was involved in making this decision?

  Probe: What types of information were used to make the decision?

Probe: What considerations influenced this decision?

Probe: Did managed care play a role?

Probe: Would the decision have been different if managed care penetration was higher in your market area?

Probe: Did hospital competition play a role?

- Have the procedures and considerations used to make adoption decisions changed over time?

  Probe: Are they expected to change in the future?

- How does the hospital monitor and control the utilization of technology?

  Probe: Protocols, formularies, utilization review, profiling?

Coordination of Technology Decision-making between Hospital and MCOs.

- Do MCO coverage decisions influence technology adoption?

  Probe: Do indemnity insurers and Medicare policies influence hospital decision-making in different ways from MCOs?

- Do technology adoption decisions affect the likelihood of obtaining MCO contracts?

  Probe: Is this a factor in the hospital's decision-making?

- What mechanisms are there for coordinating technology decision-making between the hospital and MCOs?

  Probe: Does the hospital ever consult with MCOs when making technology adoption decisions?

  Probe: Do the MCOs with which the hospital contracts attempt to influence the hospital's decisions about adopting new technologies?

- For what types of adoption decisions are MCO preferences likely to be important?

  Probe: Does this differ based on the costliness of the technology?

  Probe: Does this differ based on the visibility to patients?

  Probe: For the type of technology (drugs vs. devices vs. procedures)?

- Do MCOs impose restrictions on the use of technology that the hospital has adopted?

  Probe: What types of technology?

  Probe: How are restrictions imposed (i.e., direct prescriptions versus indirect financial incentives)?

  Probe: What is the relative importance of these types of restrictions?

Large Physician Group Protocol

Relationships with MCOs.

- With which MCOs does the group contract?

  Probe: Is the group selective in choosing which MCOs to contract with?

  Probe: Which MCO is their major source of revenues?

- What reimbursement arrangements does the group have with MCOs?

  Probe: Have your reimbursement arrangements changed recently? Are changes anticipated in the future?

- How important is managed care to the group?

  Probe: What percent of their overall patient population is enrolled in managed care?

  Probe: What percent of their Medicare patients is enrolled in managed care?

Probe: Are managed care enrollees an increasing, decreasing, or constant share of the group's patient base?

Probe: How is this expected to change in the next five years?

Coordination of Technology Decision-making between Physician Groups and MCOs.

- Is the group aware of MCO coverage policies?

  Probe: Do these influence their treatment decisions?

- Does the MCO attempt to influence their practice patterns?

  Probe: Does the MCO monitor their practice patterns?

  Probe: Does their practice patterns affect their likelihood of getting a contract?

  Probe: Does the MCO attempt to alter their practice patterns through use of direct prescriptions or indirect financial incentives?

  Probe: What is the relative importance of these types of restrictions?

- How do they monitor and control use of technologies?

  Probe: By members of group?

  Probe: By specialists patients are referred to?

  Probe: By hospitals patients are admitted to?

Device and Pharmaceutical Manufacturer Protocol

Scientific Advances Leading to New Medical Technologies.

- What role have general scientific advances played in new medical technologies (e.g., computer miniaturization, biotech, lasers, fiberoptics)?

New Technologies and the Insurance Coverage Decision.

- How important is it to prove your innovation is cost effective to insurers?
- Is cost effectiveness ever raised with venture capital firms or sources of R&D funding?
- Do you undertake any CE studies?
- What is the future of inpatient-based technologies? Does the shift to ambulatory care affect your R&D strategies?
- How do you go about getting a product covered by the various managed care plans such as Kaiser?

Insurer Payment Methods Affecting the Demand and Supply of New Technologies.

- Does the way Medicare pays for inpatient vs. outpatient care affect your R&D strategy?
- Has DRG per case payment affected the sales of your products to hospitals?
- Has DRG payment affected the use of innovative technologies like MRI, lithotripsy, stents, and transesophageal echocardiography?
- How does the impact of managed care differ from DRGs on the demand for your products?
- What is fundamentally different about managed care versus HCFA's DRG "coverage" decisions wherein hospitals generally bear the risk of using a new device or drug?
- Would HCFA's adopting outpatient APGs have any effect on your decisions?
- Would bundling all physician payments with the hospital payment change the way you market your products?

Changing Market Competition and Technology R&D.

- How do you market your products to different kinds of managed care plans?
- What is the future growth of managed care and how do you think it will affect your R&D?

- Have managed care plans been forced to adopt technologies in order to compete for patients?

- Are your marketing efforts less successful in heavily managed care areas of the country?
- Has hospital regionalization of a service reduced the number of potential purchasers of your technologies? If not, why?

- Have you shifted your marketing to any geographic area or hospital type?

- How significant is hospital joint purchasing to the marketing of your devices or drugs?

- Does the profit orientation of hospitals affect their willingness to adopt new technologies?

- In your R&D planning, do you identify technologies that might be used by providers as signals of quality?

- What would you consider a technology that hospitals could market as a signal of higher quality?

- Do you consider whether a new technology would be capable of treating multiple ailments?

- Have hospitals changed in their demand for "invisible" technologies like more durable prostheses, use of nonionic contrasts in the cath lab, lower cost pacemakers?

Medicare Managed Care and Manufacturer R&D Decision-Making.

- What percent of Medicare beneficiaries do you think are currently *enrolled* in managed care plans?

- Are you aware of some of the key conditions HCFA has imposed in approving managed care organizations? Lock-in requirements? Service coverage?

- Has your firm made any estimates about the growth in Medicare managed care over the next 5-10 year horizon? On what basis were they derived?

- Does the company foresee an upper limit to the percent of Medicare beneficiaries in managed care?

- How do your forecasts of Medicare managed care affect your future R&D decisions?
- How dependent is your current product line on Medicare? Is it particularly sensitive to the kinds of restrictions usually imposed by managed care companies (or pharmacy benefit managers)?

- Did you consider developing new product lines as a result of Medicare managed care growth? If so, which ones?

- How rigorous would you expect Medicare's managed care plans to be in covering new devices and drugs?

- Do you take managed care benefit design issues (e.g., lock-ins, coverages) into consideration in your R&D decisions?

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